EXHIBIT “A”

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,	)	Master File No. 2:12-MD-02327 MDL No. 2327 HON. JOSEPH R. GOODWIN, U.S. DISTRICT JUDGE
REBECCA DALBERG, ET AL, Plaintiffs, v. ETHICON, INC., ET AL., Defendants.	)	Case No.: 2:13-cv-09725

ORAL AND VIDEOTAPED DEPOSITION OF
MARK L. LOBAUGH, M.D.
SEPTEMBER 26, 2018

ORAL AND VIDEOTAPED DEPOSITION OF

MARK L. LOBAUGH, M.D., produced as a witness at the instance of the Defendants, and duly sworn, was taken in the above-styled and numbered cause on September 26, 2018, from 1:24 p.m. to 4:45 p.m., before Karen L. D. Schoeve, CSR, RDR, CRR, in and for the State of Texas, reported by computerized machine shorthand, at the offices of 800 East Central Texas Expressway, Harker Heights, Texas, pursuant to the Federal Rules of Civil Procedure and the procedures set forth In Re: Ethicon Inc., Pelvic Repair System Products Liability Litigation, MDL No. 2327.

It is further agreed that Rule 30(b)(5) is waived by agreement of the parties.

A P P E A R A N C E S

FOR THE PLAINTIFF: (Appeared by videoconference)

SEAN FARRELL, ESQUIRE
KLINE & SPECTER, PC
1525 Locust Street, 19th Floor
Philadelphia, Pennsylvania 19102
T: 215.772.1000
F: 215.772.0397
sean.farrell@klinespecter.com

FOR DEFENDANTS ETHICON, INC., AND JOHNSON & JOHNSON:

JEFFREY R. JOHNSON, ESQUIRE
JRJ MEDIATION
P.O. Box 3162
Edmonds, Washington 98020-3162
T: 206.234.3289
jeff@jrjohnsonmediation.com

FOR THE WITNESS:

TERRI S. HARRIS, ESQUIRE
STEED DUNNILL REYNOLDS MURPHY LAMBERTH, LLP
303 Camp Craft Road, Suite 350
Austin, Texas 78746
T: 512.476.1094
F: 512.476.7770
terriharris@steedlawfirm.com

ALSO PRESENT:

Jason Lemley, Videographer

THE COURT REPORTER:

Karen L. D. Schoeve
Certified Shorthand Reporter
Certified Realtime Reporter
Registered Diplomate Reporter
Realtime Systems Administrator

INDEX

REPORTER'S NOTE 1: Please be advised that an UNCERTIFIED ROUGH DRAFT version of this transcript exists. If you are in possession of said rough draft, please replace it immediately with this CERTIFIED FINAL TRANSCRIPT.

REPORTER'S NOTE 2: Quotation marks are used for clarity and do not necessarily reflect a direct quote.

EXHIBIT INDEX

EXHIBIT INDEX (CONTINUED)

P R O C E E D I N G S

(Deposition Exhibits 1 - 12 referenced.)

THE VIDEOGRAPHER: We are now on the record. My name is Jason Lemley. I am a videographer for Golkow Litigation Services.

Today's date is September 26th, 2018, and the time is 1:24.

This video deposition is being held in Harker Heights, Texas, in the matter of Rebecca Dalberg versus Ethicon.

The deponent is Dr. Mike Lobo -- Lobaugh.

Will counsel please identify themselves.

MR. FARRELL: Good afternoon. Sean Farrell from Kline & Specter on behalf of Mrs. Dalberg.

MR. JOHNSON: Jeff Johnson representing Ethicon and Johnson & Johnson.

MS. HARRIS: And I'm Terri Harris here and on behalf of Dr. Lobaugh.

THE VIDEOGRAPHER: The court reporter is Karen Schoeve, and will now swear in the witness.

MARK L. LOBAUGH, M.D.,

having been first duly sworn to tell the truth, the whole truth, and nothing but the truth, so help him God, testified as follows:

EXAMINATION

BY MR. JOHNSON:

Q. Good afternoon, Doctor.

Would you state your complete name?

A. Mark Lobaugh.

Q. Dr. Lobaugh, my name's Jeff Johnson. I represent Ethicon and Johnson & Johnson. We were just introduced right before the deposition started.

I'm going to ask you some questions today. If at any time I ask you a question you don't understand or need me to clarify, can you let me know that?

A. Yes.

Q. Could you just introduce yourself to the jury, just say something about your professional career and -- just so the jury can get acquainted with you as a -- as a physician?

A. Well, I attended medical school at Chicago Medical School, and I graduated in 1982.

I did a year-and-a-half of internship

in California at a UCLA affiliate program in Bakersfield, California. It was a general OB/GYN.

I left that program halfway through my second year because I had an Air Force commitment, so I fulfilled my four-year Air Force commitment as a flight surgeon in Kansas in 198- -- starting 1988 until 1992.

In 1992, I entered -- reentered into residency training at the University of Kansas and completed my residency in OB/GYN in 1996.

I have had various practice locations. I've been here in Texas now for about 15 years.

Q. Thank you, Doctor.

My understanding is that you are one of the treating doctors of the plaintiff in this case, Rebecca Dalberg, and Ms. Dalberg has filed a lawsuit against Ethicon and Johnson & Johnson.

Is that true that you're one of the treating doctors?

A. Yes.

Q. Do you understand you are not a party to this case, no one's claiming that you did anything wrong?

A. Yes.

Q. Doctor, have you had a chance to review some records of your treatment of Ms. Dalberg?

A. Yes.

Q. My understanding is that you performed surgery on Ms. Dalberg August 29, 2007; is that right?

A. Can I look at the record?

Q. Sure.

(Deposition Exhibit 9 referenced.)

Q. (BY MR. JOHNSON) I think it's Exhibit Number 9.

A. (Examined exhibit.) The date of operation was August 29th, 2007.

Q. And you might leave that out. I'm going to ask you a couple summary questions about that.

My understanding is that you performed surgery for stress urinary incontinence; is that right?

A. Correct.

Q. And you performed surgery for significant bulging of her bladder, rectum, and intestines into the vagina; is that correct?

A. Yes.

Q. Also, Doctor, just so the jury understands

what surgeries you did, you used a mid-urethral sling manufactured by Bard to treat the stress urinary incontinence; is that right?

A. According to the record, that is correct.

Q. And is that a Urotech sling made of polypropylene mesh?

A. I don't remember that much detail, other than the record says it was Bard, and so that's what I would have used.

Q. Well, we can -- if you take a look, I believe it says in the record that it was a Urotech.

A. (Examined exhibit.)

Q. Well, just in looking at the second page of the Operative Report, the last paragraph, it says it was a "Bard transvaginal tape"; is that right?

A. Correct.

Q. And was that a polypropylene mesh tape?

A. Yes.

Q. And then the record also indicates that you used Gynecare Prolift® mesh, manufactured by my client, Ethicon, to treat significant bulging of the bladder, rectum, and intestines into the vagina.

A. Yes.

Q. All right. We don't -- as I am sitting

here today, Doctor, we do not have records of your -- from your clinic or your clinic chart. It's my understanding that they either don't exist or they couldn't be found.

Could you tell the jury what the status is of those records?

A. Well, in the state of Texas we're required to keep -- it's recommended we keep records for seven years following any type of clinical exposure or encounter. And the seven years has long passed, so we officially destroy the records after seven years.

Q. So those records no longer exist?

A. Correct.

Q. The records that we do have here that you had a chance to look at pertain to your care and treatment August 24 through September 1 of 2007, and these are essentially hospital records; is that right?

A. Correct.

Q. But there are some records that you have handwritten notes on.

A. Correct.

Q. All right. Doctor, Ms. Dalberg has

brought this suit against Ethicon.

Did you tell her to sue Ethicon?

A. No.

Q. Have you ever told anyone that the Gynecare Prolift® product made by Ethicon is defective?

A. No.

Q. As you sit here today, do you have any personal knowledge of Ms. Dalberg's current medical condition?

A. No.

Q. Do you have any personal knowledge of her medical course after September 1 of 2007?

A. Yes. Well, I don't have any records, but I would've seen her for post-op follow-up after that.

Q. And my question is: Do you have any personal knowledge regarding those -- those post-op follow-ups as you sit here today?

A. No.

Q. So the knowledge that you have relative to her medical condition, care, and treatment will be the records that we have here, Exhibits 6 through 12?

A. Correct.

Q. All right. I represent Ethicon and Johnson & Johnson, and as counsel for the defendant, I'm not allowed to talk with you until the time of this deposition.

Have we spoken before?

A. No.

Q. Have we ever spoken about Ms. Dalberg's care and treatment?

A. No.

Q. Have you spoken to anyone from Ethicon or Johnson & Johnson regarding her care and treatment?

A. No.

Q. Have you spoken to any of her attorneys about her care and treatment?

A. No.

Q. Have you spoken to plaintiffs' counsel about the care and treatment of Ms. Dalberg?

A. No.

Q. Have you spoken to Ms. Dalberg herself?

A. No.

Q. All right. What did you do to prepare for the deposition, Doctor?

A. I reviewed the op report.

Q. And you've also had an opportunity to read those records 6 through 12 --

A. Yes.

Q. -- is that correct?

A. Yes.

Q. And my understanding is you've brought a curriculum vitae to the deposition; is that right?

A. Correct.

(Deposition Exhibit 1 referenced.)

Q. (BY MR. JOHNSON) Would you just take a look quickly at Exhibit Number 1? And this was a notice of deposition and subpoena for you to appear at this deposition; is that right?

A. Correct.

Q. And in response to that, did you bring anything other than your curriculum vitae?

A. No.

Q. Is that -- and that's because you don't have anything else?

A. Correct.

Q. All right. You can put Exhibit 1 away. We won't come back to that.

A. Okay.

(Deposition Exhibit 2 referenced.)

Q. (BY MR. JOHNSON) Could you take a look at Exhibit Number 2, Doctor?

A. Okay.

Q. Is that a true and correct copy of your curriculum vitae which summarizes your professional experience?

A. Yes.

Q. Is a curriculum vitae kind of a fancy word for resumé?

A. Correct.

Q. All right. My understanding is that you're here to testify as a treating doctor; is that right?

A. Correct.

Q. You have not been retained by Ethicon or Johnson & Johnson to serve as an expert witness; is that right?

A. I have -- I have not, no.

Q. And you've not been retained by plaintiffs to serve as an expert witness?

A. I have not.

Q. You mentioned briefly your education.

Where did you go to college?

A. My first year of undergraduate was at the

University of Utah in Salt Lake City, and then -- I spent one year there.

And then I went to San Joaquin Delta College in Stockton, California, for two years.

And then I went to University of California at Davis for three years, which is where I graduated.

After that, I immediately entered Chicago Medical School for medical school.

Q. And did you graduate from medical school in 1976 --

A. No.

Q. -- 1986?

A. '86.

Q. Looking at your CV, Exhibit 2, it says that you were in medical school from 1972 to '76.

That should be '82 to '86; is that right?

A. Yes.

Q. All right. Then you started -- or you did an OB -- an obstetrics and gynecology residency at Kansas from '90 through -- '92 through '96?

A. Yes.

Q. Are you board certified?

A. Yes.

Q. In what specialty?

A. OB/GYN.

Q. How long have you been certified in that specialty?

A. I was board certified in 1998, and have been so ever since.

Q. Doctor, are you licensed to practice medicine in any states other than Texas?

A. California.

Q. I saw that somewhere, maybe it was on the internet, that you are a retired lieutenant colonel from the United States Air Force.

A. From the United States Air Force International Guard.

Q. All right. And I think you gave the jury a little bit of information regarding -- regarding your service or the timing of your service.

Could you just explain to the jury your current practice?

A. Currently, I'm in solo private practice here in Texas, Harker Heights, Texas. I've had a solo private practice here for almost 15 -- about 15 years.

Q. Can you tell the jury kind of the division of your current practice in terms of the types of medical conditions that you treat?

For instance, are you still doing obstetrics?

A. I'm still doing -- the majority of my practice is obstetrics. General obstetrics, prenatal care, delivery, postnatal care.

I also do general gynecology, annual exams, problems, and that does include surgical procedures that I perform, hysterectomies, laparoscopies, sterilization procedures.

Q. Back in 2007, was the majority of your practice in obstetrics at that time as well?

A. Yes.

Q. Has that been true pretty much throughout your solo practice here in the last 15 years?

A. It's kind of varied. Back in 2007, I did have a lot more gynecology than I do -- a lot more -- significantly more gynecology than I do now.

Q. About what percent currently do you spend time treating patients for either stress urinary incontinence or prolapse?

A. It's a very small part of my practice now.

Q. How about in 2007, what --
A. It --
Q. -- what percentage was it?
A. Probably 20 to 30 percent. It was a very large part of my practice back in 2007.
Q. Is there any particular reason for the change?
A. The majority of my patients were referred to me by a urologist who did not do female urology, and that -- when that urologist left, I no longer got the referrals.

A new urologist came in to town who did female urology, so all those cases went to him. So that's why my practice pretty much ended in urogynecology at that point.
Q. And when was that?
A. That was probably, I'd have to say, around 2010, 2012 time frame.
Q. All right. Who was that new urogynecol- -- or new --
A. Urologist?
Q. -- urologist?
A. Dr. Morris. Dr. Bernard Morris.
Q. All right. Doctor, we're gonna define

some terms here for the jury.

Could you define "pelvic organ prolapse," please.

A. Pelvic organ prolapse can be defined as the relaxation of the pelvic organs which include the bladder, the uterus, and the rectum.

By "relaxation," the organs can drop or fall out of the correct position that they normally would be in.

Q. There is a term used in the records that we're gonna look at shortly and it's "pelvic relaxation."

When you used that term in a medical record, what did you -- what did you mean?

A. It's kind of a generalized term for pelvic prolapse to include -- may include or may not include, but cystocele, uterine prolapse, or rectocele.

Q. Can you tell the jury what a cystocele is?

A. A cystocele -- the way I like to describe this to my patients is to think of the vagina as a tube sock.

And the tube sock -- the bladder is a ball that sits on a hammock above this tube sock,

and when the hammock gets old or breaks or gets loose, that ball drops through and bulges into the tube sock or the vagina, and that's what a cystocele is.

Q. So that has to do with the bladder bulging into the vagina?

A. Correct.

Q. And what is a rectocele?

A. A rectocele, again, if you think of the tube sock -- the vagina as a tube sock, the rectum is a tube underneath the tube sock and there's a tissue that acts as a tent that holds that rectum in place.

When that tent gets loose, the rectum bulges into the tube sock, and that's -- that appears as a rectocele.

Q. There's another term -- because I think you fixed this in Ms. Dalberg -- "enterocele."

Can you tell the jury what that is?

A. Yeah. The -- if you look, again, at the top of the tube sock, the intestine can actually slide down underneath the bottom part of that tube sock and form a bulge higher in the vagina, and that would be an enterocele.

Q. How long have you been treating pelvic organ prolapse and these conditions you just mentioned?

A. Since graduation from residency in 1996.

Q. Is that when you -- was it during residency that you first treated pelvic organ prolapse or heard of that term?

A. Well, we hear of it in medical school. So, I mean, I -- we all know about that. And I graduated from medical school in 1986.

But to actually become involved in treating it, I did -- I did treat in residency in California. At the California hospital we did do that.

Again, I was only at that house -- that residency for a year-and-a-half. So I didn't use that training until after I finished the residency at the University of Kansas, but . . .

Q. Starting in 1996?

A. 1996 is when I really started treating it.

Q. What are the causes of pelvic relaxation or pelvic organ prolapse?

A. It's the -- if you go back to my analogy, the cystocele formation is when that hammock, for

some reason, can no longer support the weight of the ball, the bladder, and there could be a number of reasons.

Number 1 is during vaginal deliveries or childbirth, it stretches and potentially tears and weakens that tissue.

The -- you can get cystoceles even if you've never been pregnant before. So there are other mechanisms, but probably the most common is vaginal deliveries.

Same thing with the -- with the rectocele repair -- rectocele. The -- when that tent get- -- becomes weak, that tissue becomes weakened or torn or damaged, then that allows for the tent to become weak and the rectum to bulge into the vagina and form the rectocele.

(Deposition Exhibit 6 referenced.)

Q. (BY MR. JOHNSON) And just looking at one of the records for Ms. Dalberg, which I think is Exhibit 6, the second page.

A. (Examined exhibit.) Okay.

Q. Does that indicate her pregnancy -- you know, how many -- how many pregnancies she had?

A. (Examined exhibit.)

Q. Maybe it -- I saw that somewhere else.
A. No.
Q. But delivery is one of the -- the known causes of pelvic relaxation, pelvic organ prolapse; is that right?
A. Yes.
Q. Approximately how many patients have you treated for pelvic organ prolapse, Doctor?
A. In 2007?
Q. Well, to date, first.
A. Hundreds. At least a couple hundred.
Q. How about through 2007?
A. Easily a hundred. I mean, it's -- it was a significant part of my practice.
Q. Approximately how many patients have you treated for stress urinary incontinence?
A. At least a couple hundred, and that's very conservative. It's probably a lot more.
Q. And how many by 2007?
A. You know, at least over -- over a hundred.
Q. Can you just define "stress urinary incontinence" for the -- the jury?
A. "Incontinence" is defined as leaking urine, and there's two types of incontinence.

One is urge incontinence, and that's where the bladder fills up and almost starts having spasms so that the urge to go to the bathroom is fairly quick, fairly sudden, and fairly severe. In other words, these patients feel like they have to get to the bathroom or else they're gonna leak, and that's urge incontinence.

Stress incontinence is when the bladder fills up, and when they do any kind of stress such as jump, get on a trampoline, cough, sneeze, the pressures are unevenly distributed and result in leaking of urine in response to the stress.

Q. And my understanding is that you performed surgery in August of 2007 on Ms. Dalberg for both pelvic organ prolapse and stress urinary incontinence?

A. Yes.

Q. You did not do surgery for urge incontinence?

A. No. Urge incontinence is not a surgical correction; it's a medical treatment.

Q. When you start- -- first started treating pelvic organ prolapse during your residency, was

mesh available for use in those surgeries?

A. No.

Q. What did you learn as to the surgical treatment of pelvic organ prolapse during your residency?

A. Let -- can I go back and . . .

Q. Sure.

A. The -- if you include stress urinary incontinence as part of pelvic relaxation surgery, the TVT® mesh was just beginning to become available when I was a resident.

And I can't remember if I did any TVT® cases as a resident, but I know I was getting training in that through outside -- through courses outside the residency.

Q. And we'll get a little bit into the stress urinary incontinence with my client who made the product used in the -- in the pelvic organ prolapse surgery you did, so I'm gonna focus more on that.

A. Um-hum.

Q. In terms of pelvic organ prolapse, what surgical procedures were you taught during residency for treatment of that?

A. Going -- the anterior colporrhaphy and the

posterior colporrhaphy were kind of the standard treatments.

Q. Can you tell the jury what those are?

A. Going back to my tube sock analogy, basically, you would make an incision in the top of that tube sock.

You would open it up, try to expose that hammock that's damaged, and you take some stitches and you try to pull it together in trying to reforce -- reinforce that hammock so that you can -- the bladder would be basically placed back in the proper position.

And then you'd close the incision in the tube sock.

Q. Were there risks and issues that arose from that approach to fixing the tube sock, as it were?

A. We're not fixing the tube sock. Fixing the hammock.

Q. Okay. For fixing the hammock?

A. Fixing the hammock.

Yeah. Basically, you're trying to take a tissue that's already damaged or already weakened and trying to make it work. And the

biggest problem with that procedure is failure. After a few years, the failure rates were pretty high.

Q. What does that mean, "pretty high"?

A. It means that the hammock became droopy again.

Q. No. But I'm saying, what does that mean? In terms of it being a pretty high rate, what are you talking about? Are we talking about 50 percent? 40 percent?

A. I'm not sure of the exact number, but I think it was right around the 50 percent after a couple years.

Q. Okay. Eventually, synthetic mesh became available for use during the pelvic organ prolapse surgery; is that right?

A. Yes.

Q. Do you know approximately when that was?

A. I know approximately when I started it.

Q. And when did you start doing that?

A. Well, my evolution into the synthetic mesh was transitioned by using something called Pelvicol, which was a porcine dermis, and ba- -- because the basic idea is that why do you want to take already

damaged tissue and try and make it -- repair it so that it's going to function? It's never going to be anything but damaged tissue. So, in other words, that hammock is always going to be damaged tissue.

So the idea came, let's try something different. Let's try using something that can actually replace the damaged tissue, and the porcine dermis or the pig -- pig fascia was something that I used initially, and I would stitch that in to try to -- and then the theory or the goal was to have the mom's tissue grow into that and replace it and have a whole new hammock. Rather than repairing the bad -- or the old hammock, put in a new hammock.

So then it evolved to using the synthetic meshes. And I believe it was in France where they first started this. And so there was some work done in France and was encouraging.

Again, the idea is that why you -- why try to repair the damaged tissue that's making up the hammock that's holding the bladder up? Let's get some new -- new type of hammock in there that's gonna hold it in place and be done -- be done forever, reduce the failure rate.

Q. So you have per- -- you've performed a

number of these anterior colporrhaphies and posterior colporrhaphies using sutures, essentially --

A. Yeah.

Q. -- to try to repair the hammock, as you're saying?

A. That was -- that was the standard before all of these attempts came out, and that was -- that was the standard. That's the way you did it.

Q. Approximately how many of those surgeries did you do?

A. Probably a hundred as a resident.

Q. And what was your experience in terms of the success of those surgeries?

A. Well, I think my success was just like everybody else experiences. I had a high failure rate.

Q. And then at what point in time were you trying to use this Pelvicol porcine dermis, which is the -- is pig dermis?

A. Correct.

Q. Pig skin, right?

A. Um-hum.

Q. When -- what was the time period you were

trying that?

A. I went to a course in Salt Lake City. I don't remember when it was, and I don't remember who the physician was that was training us, but I'm gonna say it was a couple years after residency, so probably around '98.

Q. How long did you use that as a potential surgical technique for pelvic organ prolapse?

A. Probably for three or four years.

Q. What were your results using that?

A. I thought it -- I thought it gave a very good repair.

Q. Did you think that that was an improvement over the -- just the use of sutures in the anterior colpo- -- colporrhaphy and posterior colporrhaphy?

A. I did.

MR. FARRELL: Objection to form.

Q. (BY MR. JOHNSON) Do you know who the manufacturer of this porcine dermis was?

A. It was called Pelvicol. I'm not sure who the manufacturer was.

Q. All right. Then you got some information about use of synthetic meshes for the treatment of pelvic organ prolapse.

Approximately when was that that you first started using those meshes?

A. I would have to say it was probably around 2000. Somewhere around 2000.

Q. And approximately how many of those -- how many pelvic organ prolapse surgeries have you done using mesh?

A. Like I said, a couple hundred at least.

Q. How did you learn how to use that, Doctor?

A. The first course that I went through was put on by Bard, and I went to the course and we did cadaver labs. It was a didactic session, talking about the benefits, risks of the product, and then there was instruction on -- on doing it using cadaver labs.

Q. I take it you went to that course before you ever used mesh in -- in a surgery in a patient?

A. Correct.

Q. And so was the first mesh that you tried for pelvic organ prolapse a mesh that was manufactured by Bard?

A. I'm not sure. I can't answer that question.

Q. At some point in time, did you use

Gynemesh™ manufactured by Ethicon for your pelvic organ prolapse repairs?

A. Yes.

Q. Can you just tell the jury what Gynemesh™ is?

A. It's another form of -- of mesh for -- used for pelvic relaxation.

Q. And is that a polypropylene mesh?

A. Yes.

Q. Is the TVT®, the tension-free vaginal tape, also a polypropylene mesh?

A. I believe so, as far as I know.

Q. What's the concept be- -- behind the use of mesh for pelvic organ prolapse as opposed to just sutures or -- or using, you know, pig dermis?

A. They can --

MR. FARRELL: Objection to form.

A. The -- taking the tube sock model and opening it up and trying to find that hammock, the old-fashioned way or the traditionally method is to put sutures in that already damaged tissue and try and repair the hammock.

So the concept of using mesh is: Why do you want to try to repair something that's

already torn and old and worn? Let's put a new one in, in the likelihood that it's gonna last and continue to do -- give the support, is gonna be higher than if you're just trying to repair the torn, worn hammock.

Q. (BY MR. JOHNSON) When approximately did you start using Gynemesh™, if you know?

A. Well, I went to -- I went to a course with Gynemesh™ and it was probably somewhere around 2006, and when I -- and that was at Metroplex Hospital, I believe were my first cases.

And I had a surgeon -- Gynecare pro- -- provided this training. But they had a surgeon from Corpus Christi who was one of their lead surgeons who came and proctored me on my first three cases.

Q. And who was that, if you recall?

A. I don't recall the name.

Q. Was that -- was that mesh -- the Gynemesh™, was that the Prolift® system that you were using at that point?

A. I don't -- I'm not sure. There -- there were many different versions and improvements, and, again, it's so long ago, and I'm not doing the

surgery that I haven't really kept up on them. But I can't tell you exactly.

Q. But during this time, between 2000 when you had that course from Bard and the time that you took the course at Metroplex Hospital that -- that was sponsored by Ethicon, during that six-year time period, you were still putting mesh in for pelvic organ prolapse; is that right?

A. Well, let me just clarify. The course was not at Metroplex.

Q. Oh.

A. The surgeon came and proctored me at Metroplex --

Q. Oh, okay.

A. -- which was my hospital.

The course was somewhere else, and I don't remember where that was.

And I had -- I would -- hadn't done many mesh cases between the time I went to Bard. In fact, I'm not sure that I did any. I may have done a couple in my -- my original practice before I came to Texas, but with the assistance or direction of other surgeons.

So it wasn't until I really got to

Metroplex in 2006 that I started doing the -- the synthetic meshes on a full-time basis.

Q. For pelvic organ prolapse?

A. Yes.

Q. What about for stress urinary incontinence? What was your experience after residency in using tension-free vaginal tape, the synthetic mesh, for stress urinary incontinence?

A. I'd -- I'd have to say that really my use of -- of the tension-free tape really started about the same time.

Prior to that, one of the procedure that I was using for stress urinary incontinence was probably a laparoscopic Burch, which is using -- again, it's using a mesh, but it's a laparoscopic procedure.

Q. And was that -- that was using mesh or was that using super -- sutures, the Burch?

A. Mesh. Mesh.

Q. And what kind of mesh?

A. I don't remember the name of it.

Q. All right. Doctor, just in looking at the record, we see that you put in a Proli- -- a Gynecare mesh with a Prolift® system that was

manufactured by Ethicon; is that right?

A. Look at the -- according to the record, yes.

Q. Right.

What was the reason that you decided to use that for treatment of Ms. Dalberg?

A. At that time that was the mesh that I was using because I felt like it was the one that was most available to me. It was the one that I had the most training in, and it -- so really, it was the only mesh that I was using at that point.

Q. How many times had you put Gynemesh™ Prolift into patients prior to Ms. Dalberg in late August 2007?

A. I don't -- I don't have any way to know that number.

Q. What was the reason that you used the Bard Urotech --

MR. FARRELL: I'm sorry. Can you repeat? The doctor blipped out.

Could you repeat the answer, please?

THE WITNESS: I don't have any idea what that number is.

MR. FARRELL: Okay. Thank you.

Q. (BY MR. JOHNSON) And what was the reason that you used the Bard Urotech sling in treating this stress urinary incontinence in 2007?

A. Just a preference of the delivery method.

Q. All right. Doctor, just going back to your training from Ethicon, did you per- -- did you go to any professional education events that were sponsored by Ethicon?

A. Yes.

Q. Did you go to any professional education events sponsored by other manufacturers?

A. Yes.

Q. Which ones?

A. Boston Scientific. Was it ASI?

Q. AMS?

A. Or AMS. And the --

Q. I think you already mentioned Bard.

A. Bard. AMS, Ethicon.

And what was the other one? There's one other one.

Q. Boston Scientific?

A. The -- yeah.

Q. All right. When you attended the Ethicon professional education events, did you find those to

be helpful?

A. I found all of them to be helpful.

Q. What do you remember about any Ethicon professional education events, if anything?

A. Nothing specific.

Q. Can you give me an idea or the jury an idea of kind of how you learned at those Ethicon events?

A. There was a didactic session where they had professors giving slide presentations on the scientific background as well as proper procedures for using the product.

And then after that, there was always a practical lab or we would use cadavers to try -- or to practice on.

Q. Did you form any opinions as to whether or not the professional education events put on by Ethicon improved your professional competence?

A. Yes.

MR. FARRELL: Objection to form.

Q. (BY MR. JOHNSON) In what way did they improve your professional content -- competence?

A. Increased my knowledge.

Just being able to be with the

professional colleagues, discussing everybody's experience.

Picking up little, different ideas on how something worked for somebody, and that's a good idea, so I'm gonna try that.

And -- and then just having the experienced surgeons kind of walk you through the insertion techniques on the cadavers.

Q. So these people you were learning from were surgeons; is that right?

A. Yes.

Q. You've mentioned that there was didactic training, which is lectures?

A. Yes.

Q. Did those lectures talk about potential risks of the surgeries?

A. Yes.

(Deposition Exhibit 3 referenced.)

Q. (BY MR. JOHNSON) Doctor, if you could take a look at Exhibit Number 3, please. This is a Surgeon's Resource Monograph for the Prolift® Pelvic Floor Repair System.

And if you could just take a look at that and let me know whether or not this is

something that you probably received a copy of during your training?

A. (Examined exhibit.)

Q. Or even after your training?

A. (Examined exhibit.) It doesn't look familiar.

Q. All right. Could you take a look at page 7 of Exhibit Number 3.

A. Okay.

Q. There is a list in the middle of the page of various complications that might be associated with the use of the Prolift® system for pelvic organ prolapse surgery.

Could you just take a look at those lists and indicate whether or not you were aware of those risks at the time that you treated Ms. Dalberg?

A. Yes.

Q. Could you just read slowly for the jury what those complications were that are -- that are in this Exhibit Number 3 that you were aware of as of August 2007?

A. "Postop- -- Postoperative. Hemorrhage, Hematoma, Fistula, Infection, Urinary Retention,

Mesh Exposure, Mesh Erosion, Dyspareunia, Vaginal Pain."

Q. And then what about intra-operative complications?

A. Intra-operative complications, "Hemorrhage, Visceral Injury, Ureteral Obstruction."

Q. Where did you get the information regarding those potential complications?

A. In residency.

Q. And then did you also -- any other sources of information as to those complications?

A. Well, I mean, there's plenty of sources. There's lots of sources.

I mean, these are so commonly known that -- I mean, that's -- this is just part of the risk of the surgery.

Q. And my understanding -- and we're gonna look at the consent form later --

A. Uh-huh.

Q. -- is that there are additional risks that you were aware of as well; is that right?

A. Yeah. I mean, I don't see nerve injury on here. That was something that I'd usually talk to them about.

Q. And we'll go through the consent form, which -- which discusses a number of different risks.

MR. JOHNSON: Can we go off the record?

THE VIDEOGRAPHER: Going off the record. The time is 2:07.

(A recess was taken from 2:07 p.m. to 2:14 p.m.)

THE VIDEOGRAPHER: Back on the record. Time is 2:14.

(Deposition Exhibit 4 referenced.)

Q. (BY MR. JOHNSON) Doctor, could you take a look at Exhibit Number 4, please.

A. Okay.

Q. And this is a chart of Potential Risks of Non-mesh Pelvic Organ Prolapse Surgery.

Could you just take a look at that list and tell me whether or not as of August 2007, you were aware of the risks of non-mesh pelvic organ prolapse surgery that are identified on Exhibit 4?

A. (Examined exhibit.) Yes.

Q. Where did you get that knowledge?

A. Residency.

Q. Were you aware that those risks set forth on Exhibit 4 could be either temporary or chronic?
A. Yes.
Q. Were aware that the risks set forth on Exhibit 4 could be either mild, moderate, or severe?
A. Yes.
Q. Where did you get that knowledge?
A. Again, from residency training.
(Deposition Exhibit 5 referenced.)
Q. (BY MR. JOHNSON) Doctor, if you could take a look at Exhibit Number 5, and I'll represent to you that the left-hand of Exhibit Number 5 is the same as what's on Exhibit Number 4, and the right-hand side has to do with potential risks of mesh pelvic organ prolapse surgeries.
Could you look at that list and tell me whether or not as of August 2007, you were aware of those risks on the Mesh side of Exhibit Number 5?
A. (Examined exhibit.) Yes.
Q. Were you aware -- or -- and what was the source of that knowledge?
A. From the training courses as well as reading the literature.
And the mesh surgery is an anterior

repair.

Q. Is a what?

A. It's an anterior repair. It's the same -- it's the same procedure as it was done traditionally, just with a different method.

So any risk that was present not using mesh could also potentially be present using mesh.

Q. And were there some other potential risks involving using mesh that you learned as well such as the erosion or exposure?

A. Yes. And that was probably the one complication which was greater or the one that I emphasized the most to the patients is the potential for erosion of the mesh which could potentially require additional surgeries.

Q. And we'll go through your consent form.

As of August 2007, were you aware that the risks set forth on Exhibit Number 5 pertaining to mesh pelvic organ prolapse surgeries could be acute or chronic?

A. Yes.

Q. Were you aware they could be mild, moderate, or severe?

A. Yes.

Q. Doctor, you had an opportunity to -- I'm gonna change subjects.

You had an opportunity to treat Ms. Dalberg; is that right?

A. Yes.

Q. And you have -- there's a record. It's Exhibit Number 6.

Could you just take a look at that and just tell the jury what Exhibit Number 6 is?

A. This is my preoperative history and physical.

Q. Whose handwriting is on this?

A. Some of it's mine and some of it's probably my medical assistant.

Q. It looks like the -- the name, Rebecca Dalberg, the date, the height and weight and blood pressure, looks like to be in a different handwriting than everything else.

A. Yes. Well, I think under Previous Surgeries that was -- I think that might be the same.

Q. Okay. In any event, could you just go through quickly, because I can't read all of these things, and just tell the jury what -- what is set

forth on page 1 of Exhibit Number 6?

A. Could you repeat the question?

Q. Sure. Could you just go through -- there's handwriting. I can't read it all.

Can you just go through and indicate what is on this form?

A. Well, the patient -- patient's name.

The Primary Care Physician, she didn't have one. We don't have the -- or we just didn't fill it in.

The Identifying Data, she's a 59-year-old.

Chief Complaint, we didn't fill that in because we knew it was pelvic organ prolapse.

The History, she had a previous bladder surgery in 1996.

Q. And you're looking at page 2 of Exhibit 6 right now?

A. Oh, correct. That's correct.

Q. Okay. Anyway, go -- why don't you go ahead and continue.

A. Had the incontinence at that time.

Continues to have stress urinary incontinence.

The leak point pressure was 66.

She had a low urethral -- UPP, which is urethral pressure profile, and that's all done on urodynamic testing in my office.

Q. I have one question about that.

Under History, does it say "had to repair cystocele"?

A. Yes.

Q. And that's why she had the bladder surgery in 1996, according to this history?

A. Yes.

Q. All right. Go ahead.

A. "Past Medical History or Past Medical Problems: Hypertension, SLE, headache.

"Medications: See the list." So there was another list that she had with her record.

"Over the Counter Prescriptions: None.

"Previous Surgeries," she had a cholecystectomy, an exploratory laparotomy, an appendectomy. She had a hysterectomy with BSO. I can't --

Q. Is that "tonsil"?

A. "Tonsil," I guess.

Next one's "carpal tunnel." She had four vaginal deliveries, one knee surgery.

Allergies, she's allergic to vitamin C, E, aloe vera. I can't see what the next allergy is.

Her Gynecol- -- "Gynecological History: Last PAP" -- well, she had a hysterectomy, so she didn't have a PAP.

Her mammogram was a year ago.

She's not on any contraception.

Then the Review of Systems all were checked "negative."

Q. All right. And so there is a reference under Previous Surgeries to her delivering four children; is that right?

A. Yes.

Q. What tests did you do to determine in your office that she had stress urinary incontinence and this LPP of 66 and low VPP?

A. We did urodynamic testing in my office, and that's using a -- a machine where -- place a catheter in the bladder, one in the rectum.

We fill the bladder up with fluid and measure pressures, have the patient cough, strain

and void, and then we can measure the pressures in the urethra, and it sort of gives us an idea of the function of the urethra and if they're a candidate for a mid-urethral sling.

Q. And based on what you have in this note, was she a candidate for a mid-urethral sling?

A. Yes.

Q. What significance, if any, was the fact that she had had previous bladder surgery to repair a cystocele?

A. That is signi- -- significant because she had the previous traditional approach trying to use the -- her own tissue, her own hammock to repair this dropping bladder, and it failed.

Q. And why was that significant to you?

A. Because that -- to me, that told me that it didn't work, so she needed something else.

Q. Did that play any role -- or strike that.

Did the fact that she had the prior failed surgery play any role in the decision-making process to use mesh for the pelvic organ prolapse?

A. At this point, all of my anterior repairs were being done with mesh. So I'd have to say no, it didn't play any role.

Q. But that was -- would that have any impact on whether or not mesh was indicated?

A. No.

Q. No.

Because you were gonna use it anyway?

A. Right.

Q. And what was the reason you were going to use it anyway?

A. I just believed it was a better approach to not try to repair damaged tissue because it was probably not gonna work, and in my opinion, trying to replace that hammock was something that was gonna be stronger and longer lasting, forever lasting was a better approach.

Q. Doctor, when you used the Gynemesh™ Prolift System for the pelvic organ prolapse, at that time did you believe that that was the approach that gave you the best chance of success for your patient?

A. Yes.

Q. All right. Could we take a look -- let me ask you some questions about informed consent, and I'm gonna get to your consent form, Exhibit Number 7, but let me just ask you.

Can you just tell the jury what the concept of informed consent means?

A. The patient needs to have all the information available, or as much as possible, to allow them to make the decision that is best for them. And so what we try to do is we try to describe the procedure that we're recommending.

That's why I use my tube sock analogy, tent, hammock. You know, people can understand that stuff.

And then once we describe the procedure, we tell them the benefits of the procedure, how this will help them, or how this might help them, but we also give them the risks of the procedure, the things that may not necessarily be desired such as failure, another surgery, erosion, for example.

And so the patient has to really make that decision on what's gonna be the best course of treatment for them.

Q. Would it be fair to say that you discussed the alternatives, benefits, and material risks with Ms. Dalberg before her surgery?

A. Yes.

Q. Is providing an --

MR. FARRELL: Objection; form.

Q. (BY MR. JOHNSON) Is providing an informed consent required under Texas law?

A. Yes.

Q. Doctor, in 2007, what was your approach to make sure a patient was able to make an informed decision?

A. Just to talk to them. Talk to them and then describe all the risks and benefits.

Ask them if they understood.

Ask them if they had any questions.

And, you know, again, describe the condition that they have.

Describe the procedure or the options.

(Phone interruption.)

A. Describe the options that are available, and then try to describe the procedure as best I can.

And then talk about the benefits and also talk about the potential risks.

Q. (BY MR. JOHNSON) Did your -- did you do the informed consent discussion yourself?

A. Yes.

Q. Did you ever have your staff involved in that?

A. In the discussion?

Q. Right.

A. No.

Q. Did you have videos for your patients at all?

A. No -- oh, videos? Yes.

Educational videos?

Q. Yeah, for the patients to look at before a surgery like this?

A. We -- we did have some. Not too many of the patients really took us up on it.

Q. Do you know whether or not in this case a video would have been made available to Ms. Dalberg if she had wanted to review it?

A. I do not know.

Q. Did you have any handouts that you provided to patients --

MR. FARRELL: I'm sorry. What was the Doctor's answer, please? It blipped out.

MR. JOHNSON: He did not know. He did not know, Sean.

MR. FARRELL: Thank you.

Q. (BY MR. JOHNSON) Did you have any handouts, either company, ACOG, or other handouts regarding pelvic organ prolapse for patients?

A. I don't remember.

(Deposition Exhibit 7 referenced.)

Q. (BY MR. JOHNSON) Could you take a look at Exhibit Number 7, Doctor, and can you tell the jury what Exhibit Number 7 is?

A. (Examined exhibit.) That's a Disclosure and Consent Medical and Surgical Procedures.

Q. That's the first -- the first page.

What are the next two pages?

A. Pelvic Reconstruction Consent.

Q. What is the reason that you had two separate consent forms for Ms. Dalberg in this particular situation?

A. The first one is the Texas Medical Disclosure Panel's form. So that was the State of Texas form.

Q. And what was -- what are the last two pages?

A. The last two pages are my form.

So I tailored this to my discussion and how I -- I discussed with the patient.

Q. For purposes of -- well, strike that.

So how -- can you just tell me the process by which this form -- both of these forms would be provided to Ms. Dalberg, and what process would go -- she would go through before signing?

A. When the patient would come for the pre-op appointment -- this -- this -- now, there is some variability to this, but this is pretty much the standard.

The patient would come for the pre-op before surgery and we would sit down and review everything that had already been talked about and discuss the procedure, discuss the risks, the benefits.

And if the patient had no more questions, then the medical assistant would come with the consent, have her read the sent -- consent, and sign it.

Q. Would you actually go through these forms with -- would you have gone through -- strike that.

Would you have gone through these forms with Ms. Dalberg?

A. I don't take the form in and go in -- in -- through the form. But in my discussion, I

cover all these bullet points.

Q. All right.

A. And then the patient is asked to read it over and sign it.

Q. And we see that the surgery was August 29th.

And the History and Physical that you did, which is Exhibit 6, was August 24th, 2007; is that right?

A. Yes.

Q. And looking at the bottom of the first page of Exhibit Number 7, which are the consent forms, is there a date?

A. There is not a date.

Q. Well, on the -- on the first page of the -- the front page of Exhibit 7, is there a date?

A. That one is dated August 24th.

Q. And she signed that; is that correct?

A. Yes.

Q. Would the -- would she receive both the top page, the Texas medical consent form, and the back two pages, the Pelvic Reconstruction Consent forms, on the same day for signature?

A. Usually not.

Q. Can you tell me -- or can you tell from the information we have when she signed the Pelvic Reconstruction Consent form?

A. The Texas form would be -- would be signed at the hospital on the day of surgery, and the -- my form would have been signed in the office at the day of the pre-op.

Q. And based on looking at this, it appears that the Texas form was actually signed on the day of the pre-op as well; is that right?

A. Apparently so, yes.

Q. All right. And in terms of the date when she would have signed your form, based on your normal custom and practice -- or ordinary custom and practice, would that form have been signed on August 24, 2007?

A. Yeah, and I must say that --

MR. FARRELL: Objection; form.

A. -- this is the way that we're doing the consents now.

Back in 2007, we may have actually had them sign the Texas form and my form at the same time because that was a different hospital than what I'm practicing now.

And just trying to think about this, they may have actually provided these Texas forms for our office to get before they came to surgery. So that's possibly why the dates are different.

Q. (BY MR. JOHNSON) All right. I guess my question is: Based on your ordinary custom and practice, is it likely that Ms. Dalberg signed the Pelvic Reconstruction Consent form on August 24, 2007?

A. Yeah -- was that the pre-op date?

Q. Yes.

MR. FARRELL: Objection; form.

A. Yes.

Q. (BY MR. JOHNSON) And why is -- why is that likely?

A. Because that's when we had -- that's when we reviewed all the risks and benefits, reviewed the procedure, and that's when we got the consents signed.

Q. So just taking a look at your Pelvic Reconstruction Consent form, which is the last two pages of Exhibit 7, Doctor, it appears that you provided her with a -- information regarding risks; is that right?

A. Yes.

Q. And the risks of the surgery and also risks of using the graft material, either the T- -- either the tension-free tape or the sling or the pelvic mesh for the pelvic organ prolapse; is that right?

A. That's correct.

Q. Okay. Can you tell the jury what the risks were that you described to Ms. Dalberg prior to her surgery based on your ordinary custom and practice in August of 2007?

A. Anytime you have surgery --

MR. FARRELL: Objection; form.

A. Anytime you have surgery, there's risk -- risk of infection, bleeding, injury to the bowel, bladder, nerves, ureters.

Anytime you have this type of surgery, the biggest concern that I have is there could be potential erosion of the mesh -- mesh through the -- through the vaginal skin, and if that were to happen, the -- an additional procedure would have to be performed in order to address -- address the erosion.

Anytime you have this surgery, there's

a potential for scarring which cause -- could cause pain, particularly with intercourse, and these are all conditions that would have to be potentially addressed after post-op recovery time pain.

Q. (BY MR. JOHNSON) And did you have any discussion regarding potential urinary symptoms, incontinence or retention?

A. Well, specific- -- whenever I do a sling, I always tell them that there is a possibility that you may not be able to empty your bladder. You may have some -- some urinary retention. It's usually temporary. It's very unusual for it to be permanent, and if something like that happens, usually you have to wear a catheter.

And I also -- again, I always -- I already mentioned the injury to the bowel, bladder, or ureter nerves. And if there is a bladder injury, you'll have to have a catheter for an extra -- a week or two.

Q. Just in looking at this form, Exhibit 7, and the risks, there's a statement here -- and it's the fifth bullet point down -- that there could be "Allergy or sensitivity to the graft material resulting in your body rejecting the graft. This

may necessitate an additional surgery to remove the graft and repair any defect that results from the graft material."

What would you have told Ms. Dalberg about that?

A. Well, I usually just discuss the erosion and include that as part of the erosion, that the -- the graft may potentially be exposed and it'll have to be fixed, potentially removed.

Q. Looking at the next bullet point, it says that, quote -- well, strike.

The next bullet point says, "Infection of the graft material may require removal of the graft material. Additional surgery may be needed to correct a defect caused by the removal of the graft material."

Is that information that you provided to her as well?

A. I'm not sure if I specifically provided that.

I really didn't find infection of the graft to be a very common thing. I -- I didn't think I ever had one that was infected.

Q. You don't think that's something that you

emphasized?

A. Probably not.

Q. But she obviously had that information from the form itself?

A. Yes.

And, again, I -- I briefly talk about infection as an overall potential complication. So I -- I include that as -- within that overall scope of possible infection.

Q. Then the next bullet point says, "Occasionally the graft may erode through the adjacent tissue requiring additional surgery to repair the erosion. Rarely the graft will need to be removed."

And I think that's what you've said you've already discussed with her?

A. Yeah.

Q. Or that you would have discussed with her for sure?

A. Yes.

Q. And then two more bullet points down, it says, "Reduction of loss of ability to control flow of urine, urinary incontinence."

Is that something that you as part of

your actual verbal discussion would talk about with -- with -- would've talked about with Ms. Dalberg?

A. Well, she already had incontinence. So we were talking about -- more about the repair in correcting the incontinence and that the possibility that the repair may not work. Although it was 85 percent effective, there was still 15 percent that it was not gonna work.

Q. And so the final bullet point there is, "Your condition may not be cured and may recur."

A. Yes.

Q. Is that something you discussed with her?

A. Well, like I just said, there's a 15 percent failure rate in -- in sling. Proce- -- in mid-urethral sling procedures, so there's -- there's always that possibility that the surgery is not gonna correct the problem.

Q. Was it your practice at that time to give the patient an opportunity to ask any questions?

A. Oh, yes. Yeah, we always -- we had an open -- open dialogue. They could ask whatever question they wanted to.

Q. What would be the reason that you'd have

the consent form signed on August 24th, five days before the surgery?

A. Well, we try to do it at the pre-op appointment, because that's -- you know, that's their last shot at really trying to get the major opportunity to answer their questions.

They can ask -- answer -- I always see them in pre-op and ask them, "Well, do you have any more questions? Is there anything else you want to ask?"

But really, the final discussion is at the pre-op appointment.

Q. Dr. Lobaugh, do you have an opinion to a reasonable degree of medical certainty as to whether or not you provided an informed consent to Ms. Dalberg?

A. I have no uncertainty. I'm -- I'm --

MR. FARRELL: Objection to form.

A. -- convinced that I provide informed consent to all my procedures.

Q. (BY MR. JOHNSON) Yeah.

How would you just -- how would you characterize your consent, robust, or in some other way?

MR. FARRELL: Objection to form.

A. I -- I -- I would provide my consent as a patient friendly discussion of the -- of the realistic expectations of the procedures and the potential problems. And that's how I'd describe it.

Q. (BY MR. JOHNSON) All right.

MR. JOHNSON: Could we go off the record real quick?

THE VIDEOGRAPHER: Going off the record. Time is 2:39.

(A recess was taken from 2:39 p.m. to 2:40 p.m.)

THE VIDEOGRAPHER: Back on the record. Time is 2:40.

(Deposition Exhibit 8 referenced.)

Q. (BY MR. JOHNSON) Doctor, Exhibit Number 8, is this just a history and phys- -- this is your history and physical that you did on August 24 that gets in -- gets filed into the hospital record; is that right?

A. Correct.

Q. Okay. Could you take a look at Exhibit Number 9? This is your Operative Report; is that right?

A. Yes.
Q. And what was your preoperative diagnosis?
A. "Stress urinary incontinence" is Number 1.
Number 2, "Low Urethral Pressure Profile."
Number 3, "Cystocele."
Number 4, "Rectocele."
And Number 5, "Vaginal Prolapse."
Q. And what was your postoperative diagnosis? Was it the same?
A. Yes.
Q. What operation did you actually perform?
A. Number 1, "Transvaginal tape placement."
Number 2, "Repair of rectocele."
Number 3, "Vaginal extracorporeal colporrhaphy."
Number 4, "Anterior colporrhaphy."
Number 5, "Mesh, 2 units."
Number 6, "Cystoscopy."
Number 7, "Enterocele repair."
Number 8, "Perineoplasty."
Q. Okay. Can you just tell the jury briefly how you use mesh to perform the anterior repair for the cystocele and the posterior repair for the

rectocele and enterocele?

A. The -- you want me to describe the procedure?

Q. Yeah, just briefly. Just kind of how you -- how you do it.

A. Okay. So going back to my tube sock model, I make an incision in the top portion of the tube sock and I open up the tissue and basically place the mesh underneath the hammock that I described earlier and elevate the ball, and then attach the mesh to the ligaments, the sides, and then close up the tube sock.

The posterior repair, I make an incision in the bottom portion of the tube sock, try to find the -- dissect out the -- the tent and put the mesh in over the tent and then attach the mesh to the supporting tissue and then close up the tube sock.

Q. So you used two different pieces of mesh?

A. Yes.

Q. And then it says in the Operative Note that you trimmed some of the -- the mesh after each of those -- the anterior and the col- -- and the posterior colporrhaphies.

How did you learn how to -- how to do that?

A. The -- well, the mesh comes in one size, and you trim the mesh to -- to fit the size of the hammock or the size of the tent, and then that's what you place into the -- to replace that -- those.

Q. Did you inspect the mesh before you implanted it?

A. I mean, in what way?

Q. Well, did you note any fraying of the mesh?

A. I -- I don't remember. I mean, I can't -- I can't imagine not expect- -- inspecting it. If there was some obvious damage, then I -- I would have noted it, but I don't recall.

Q. Either would have noted it or asked for a new kit?

A. Yes.

Q. Is there any evidence in the -- in the records you have from that surgery that there was any fraying of the mesh?

A. No.

Q. Any roping of the mesh?

A. No.

Q. Any curling of the mesh?
A. You mean prior to inserting it?
Q. Yeah, prior to inserting it?
A. No.
Q. And any degradation of the mesh?
A. No.
Q. Did you try to put the mesh in tension-free?
A. Yes.
Q. Why is that?
A. That was the correct technique is to do a tension-free placement, because keeping it tension-free was supposed to reduce the risk of contracture and was supposed to be a better, long-term repair.
Q. Doctor, did you comply with the standard of care in your treatment of Ms. Dalberg by use of the Prolift® system for repair of her pelvic organ prolapse in 2007?
A. Yes.
Q. Do you stand by your decision to use the Gynecare Prolift® mesh to treat her pelvic organ prolapse?
A. Yes.
Q. Okay. Have you given the opinions that

you've provided today and the testimony you've provided today to a reasonable degree of medical certainty?

A. Yes.

MR. JOHNSON: Thank you.

I'll reserve the rest of my time.

Let's go off the record.

THE VIDEOGRAPHER: Going off the record. Time is 2:45.

(A recess was taken from 2:45 p.m. to 2:50 p.m.)

THE VIDEOGRAPHER: Back on the record. Time is 2:50.

EXAMINATION

BY MR. FARRELL:

Q. Doctor, I was introduced to you briefly previously. Sean Farrell here on behalf of Mrs. Dalberg.

As counsel for defense has indicated, there is no claim against you or any lawsuit pending against you.

You understand that, correct?

A. Yes.

Q. Doctor, have you ever -- have you ever

testified previous to today?

A. Yes.

Q. In what capacity?

A. As a treating physician.

Q. Okay. Have you ever testified on behalf of Ethicon in any matter prior -- or prior to today?

A. No.

Q. Okay. Have you ever testified previously, like today, where you have been the implanter of an Ethicon product in another patient?

A. Yes.

Q. How many times did you testify in instances such as that?

A. Once.

Q. And was that this year or was it previous to this year?

MS. HARRIS: Probably last year.

A. Last year.

MS. HARRIS: Probably.

Q. (BY MR. FARRELL) Last year. Okay.

Doctor, what did you do to prepare for your testimony here today?

A. Read over the record that was provided for me.

Q. And when did you have the opportunity to actually review the record?

A. Last night.

Q. Okay. So last night and prior to today's -- today's deposition when you saw a few of the exhibits, that was the only time you had the opportunity to review records relating to your testimony?

A. Yes.

Q. Okay. And, Doctor, is it fair to say you have no independent recollection of your interactions with Mrs. Dalberg, correct?

A. Correct.

Q. And you're -- you're relying on the records that you reviewed last night and earlier today; is that correct?

A. And also my experience of my normal activities.

Q. Okay. Did you have any discussions with anybody prior to your testimony here today regarding your testimony?

A. No.

Q. Doctor, did you ever serve as a preceptor for Ethicon?

A. Not for a mesh.
Q. For what?
A. I may have served as a preceptor for thermoablation.
Q. All right. Did you ever serve as a consultant for Ethicon?
A. No.
Q. And the thermoablation that you referenced, did -- referenced, what -- what type of procedure is that?
A. That's an endometrial ablation.
Q. And, Doctor, I bel- -- correct me if I'm wrong, but I believe you said you've been in practice since 1982; is that correct?
A. That's incorrect.
Q. That's when you -- '82 is when you graduated medical school?
A. I graduated from medical school in 1986.
Q. '86. I'm sorry.
And how many years have you been in practice as a obstetrician/gynecologist?
A. I completed residency in 1996, so since then.
Q. And I believe you indicated that you're

board certified in obstetrics and gynecology, correct?

A. Yes.

Q. You have not obtained any additional certification for female pelvic medicine and reconstructive surgery; is that correct?

A. That's correct.

Q. Do you intend to pursue that additional certification?

A. No.

Q. I believe, and you can correct me if I'm wrong, you indicated that your current practice consists, in the majority, of obstetrics; is that correct?

A. That is correct.

Q. And could you give me an estimate of the percentage that obstetrics currently comprises your practice?

A. 80 percent.

Q. And what about in 2007, what percentage was obstetrics -- obstetrics had comprised of your total practice?

A. 60 percent.

Q. 60?

A. 60.

Q. And I believe you indicated the reason why there was more -- a focus away from obstetrics back in 2007 was that the urologist that was located in your vicinity there in Texas did not handle female patients; is that correct?

A. That's correct.

Q. And, Doctor, you went over some of the procedures -- premesh procedures that you undertook during medical school, residency, and so on; is that correct?

A. Correct.

Q. Okay. And I believe you indicated you would do anterior and posterior colporrhaphies for pelvic organ prolapse; is that correct?

A. That's correct.

Q. And what was the procedure that you indicated that you would do for stress urinary incontinence?

A. Well, there were a number of procedures. We -- for quite a while, I did the Burch procedure, which is a urethropexy.

Before I started -- I used that procedure predominantly before I started doing the

TVT®s and TOTs.

Q. Doctor, do you still have any occasion to perform the surgeries without the use of mesh?

A. Yes.

Q. Okay. What type of circumstances would you move forward with performing a surgery to address pelvic organ prolapse without the use of mesh?

A. If I have a patient that presents with the symptoms of cystocele or rectocele and the examination confirms a significant cystocele or rectocele, I'll perform the anterior colporrhaphy and/or posterior colporrhaphy, depending on the clinical presentation.

Q. So what percentage of your current surgical practice would that type of procedure or procedures represent?

A. Less than 10 percent.

Q. And what about the other 90 percent? Would they all be comprised of mesh or would you use other methods besides mesh?

A. Can you repeat the question?

Q. The other 90 percent of the surgeries you would perform for pelvic organ prolapse, would they

consist solely of mesh approach or would there be other approaches that you also utilize?

A. I'm not using any mesh for surgeries at this point except for mid-urethral slings.

Q. Doctor, are there any approaches, short of surgery, that can be utilized to address pelvic organ prolapse?

A. Yes.

Q. And what would they be?

A. Physical therapy is one option. We offer that to our patients as an initial form of therapy. We have a really good -- a very good female physical therapy group here in our community, and so they can work with the patients.

Another nonsurgical approach is pessary, and that does not seem to be favored by, really, any of the patients.

Q. Doctor, you indicated that you received training from Ethicon; is that correct?

A. Yes.

Q. Okay. And from the defendants' fact sheet that I was provided with, it looks like you attended a training in March of 2007 at South Miami Hospital relating to TVT-Secur and Prolift® preceptorship.

Do you recall that?

A. Yes.

Q. Okay. Then that was followed by the May 2007 training at the Metroplex Hospital in Killeen, Texas.

Do you recall that?

A. Yes.

Q. Okay. I believe you testified that it was your recollection it took place in 2006.

Does the fact that it was held on May 16th, 2007, refresh your recollection as to when the training at the Metroplex Hospital took place?

A. That -- that doesn't surprise me. So, again, I was trying to recollect over 10 years ago of when these dates were is not -- not the easiest, but it does make sense that I went to the didactic course in -- in March, and then the preceptor followed after that.

Q. Do you recall the number of days of training in South Miami lasted?

A. Probably three or four days. It was over a long weekend.

Q. And what about the -- the training that took place at the Metroplex Hospital?

A. That was a one-day training session. I had three cases that I had scheduled, and the physician from Corpus Christi assisted me and instructed me on those three cases.

Q. So the training that took place in Miami, did that involve didactic and cadaver labs?

A. To my -- the courses always had a didactic portion with a training lab. I don't specifically remember how that course was set up, but I'll have to just say that the way these courses were set up, that was typical how they -- how they were done.

Q. And what did the training at the Metroplex -- Metroplex Hospital entail, to your recollection?

A. Again, that was -- I had three cases at the hospital, and the training surgeon who was there was assisting me on the cases and in- -- and instructing me and proctoring me through the cases.

Q. And those three cases, do you recall what products you used? Would that be the Prolift® in each of them or were you also using the TVT-Secur?

A. Well, yeah, it was all three of them.

Because if Gynecare is sending a proctor, I'm gonna be using Gynecare's product.

Q. How did you learn about the course being offered in Miami?

A. I don't recall.

Q. Okay. Were you approached by a representative from Ethicon in order to attend that training?

A. It probably was made available through a representative, because at that time I had a very active practice and a very active interest in pelvic prolapse. So I was getting a lot of invitations through a lot of different courses, and I attended a lot of CMEs on different courses.

So it was probably -- I just kind of at that time was sort of in that circle where I was getting that information provided to me routinely.

Q. Okay. And the same question with regards to the training at the Metroplex Hospital, was that communicated to you by a representative from Ethicon?

A. Most likely. It was probably set up through -- through the representative.

Q. Did Ethicon pay for the cost of your attendance at the training program in South Miami?

A. Most likely they did or at least the

majority of it.

Q. I'm sorry, Doctor, you broke up.

A. At least the majority of it.

Q. Did Ethicon pay for your travel to and from the training in South Miami?

A. Most likely they did. I don't know for sure, but most likely they did.

Q. Were you reimbursed for any meals that were related to your travel to and from the training in South Miami?

A. I don't recall, but I know that the meal -- a lot of the meals were provided.

Q. Did you know the instructor or instructors at the South Miami Hospital training prior to you attending that course?

A. I believe the -- one of the main instructors was Bill Sayee, and I had -- I did know Bill Sayee. I had been at quite a few conferences previously where he was a presenter.

MR. JOHNSON: How do you -- how do you spell his name?

THE WITNESS: S-a-y-e-e. S-a-y-e-e is his last name.

MR. JOHNSON: Thank you.

Q. (BY MR. FARRELL) And what about the instructor or the proctor for the Metroplex Hospital trainings? You indicated that he was a physician from Corpus Christi.

You don't recall his identity, correct?

A. I do not. And I did not know him before he came to proctor me.

Q. Correct me if I'm wrong. I believe you indicated that you did have some training in pelvic organ -- organ prolapse mesh through Bard prior to the training with Ethicon; is that correct?

A. I believe so, yes.

Q. But you stated that you only did one or two implantations of the Bard; is that correct?

A. I'm not sure if I used any of the Bard product on any of my own patients.

Q. Okay. And you used the Bard during your residency for the 1-1/2 years in California prior to fulfilling your commitment with the military?

A. That is incorrect. There was no mesh used in my residency in California.

Q. Okay. So the training for the mesh with Bard, to the best of your recollection, you don't

believe that you ever used that to implant into any of your patients for pelvic organ prolapse surgery; is that correct?

A. I'm not sure if I used it after the course. I think somewhere in the time frame between 2006/2007 and when I quit using the mesh in 2010/2012, it's somewhere during that course I believe I did use the Bard product.

Q. Prior to the training in March of 2007, had you ever implanted Prolift® in any of your patients?

A. No.

Q. Had you ever observed a Prolift® implantation prior to your training in South Miami in March of 2017?

A. I don't believe so.

MR. JOHNSON: You said 7- -- Counsel, you said March of 2017. I think you misspoke.

MR. FARRELL: I did. Thank you. 2007. Thank you.

Q. (BY MR. FARRELL) Doctor, is it fair to say that when you went for the training in South Miami in March of 2007, that was the first time that you got an in-depth information regarding the

Prolift® product?

A. I would say that's not correct. I mean, I certainly had been exposed to the literature and looked at videos and had gone to courses before where they had talked about it. So I had a pretty good idea of what it was about before I went down to the course in South Florida.

Q. But that course -- but that course would have been your first hands-on experience with the product; is that correct?

A. Yes, I believe so.

(Phone interruption.)

Q. (BY MR. FARRELL) And that would be inclusive of the didactic training you indicated?

I believe you said you might have seen a video; is that correct?

MR. JOHNSON: Object to the form.

A. Yes.

Q. (BY MR. FARRELL) Okay. And you also participated in the cadaver labs; is that correct?

A. Yes.

Q. You were asked previously about material that you would have been provided with at the training.

Do you recall whether or not you were provided with any materials, written materials?

A. Oh, I'm sure I was provided with materials, but I don't recall which ones.

Q. Okay. To the best of your recollection, do you still have any of the materials from that training?

A. I do not.

Q. Do you recall whether or not you reviewed the Instructions For Use relating to the Prolift® as part of the training in South Miami?

A. It was probably part of the didactic training. So I think that that was a presentation within the didactic training.

Q. And you indicated that you -- there was a presentation made by some of the professors there, correct?

A. As far as I can remember. I mean, I kind of --

Q. Do you recall anything -- sorry.

A. I don't -- I don't really recall the details of the course, but just when I'm speaking of these courses, I'm speaking on generally how they were run.

They were all pretty much the same, and it started off with the didactic session which would go over the product, discuss the procedure, discuss the steps that were needed in order to use the product, and then the follow-up would be a cadaver lab to reinforce the didactic portion of the -- of the course.

Q. Was the information presented to you at the South Miami training important to you so that you could use that information as part of your -- of your decision regarding whether or not you wanted to use the Prolift® with any of your patients?

A. I pretty much already knew I wanted to use the Prolift®, so it re- -- reinforced my instruction on the product, and so it was very beneficial to reinforce those areas that I -- I already knew and to add additional information to the areas I didn't know.

Q. And, Doctor, did you presume that the information that was being provided to you by the training in South Miami would be accurate, to the best of Ethicon's knowledge, for you --

A. Yes.

Q. -- to use their product?

A. Yes. I counted on that.

Q. Doctor, did you believe that the information that was being presented to you at the Ethicon training in South Miami would be fair and balanced in the sense that it would tell you both the positive aspects of implanting your patients with Prolift® and also tell you about the risks or actual problems that they were aware of so that you could balance those in your mind?

MR. JOHNSON: Object --

A. Yes.

MR. JOHNSON: I'll object to the form.

Q. (BY MR. FARRELL) Doctor, did you presume that any risks that Ethicon knew about, especially any serious risks they knew about relating to the Prolift®, would be presented to you as part of the presentation you received in South Miami so that you would have a full understanding what the risks were?

A. I counted on that information being presented.

Q. Doctor, is it fair to say that prior to your Prolift® training in South Miami, you had not surgically implanted any large volume of polypropylene mesh in a woman's pelvis like that of

the Prolift®?

A. Yes, that is -- that is an accurate statement.

Q. Doctor, during the presentation that was pre- -- given to you in South Miami relating to the Prolift® product, do you recall whether or not you were actually provided with information about clinical studies that had been done with the Prolift® and the prototypes for the Prolift® so that you'd have some data relating to any such studies?

MR. JOHNSON: Object to the form.

A. I don't recall if that was part of the course or not.

Q. (BY MR. FARRELL) Doctor, did you presume that any data that was presented to you during the training in South Miami would be accurate and that Ethicon would be presenting to you actual data from any studies that were conducted?

MR. JOHNSON: Object to the form.

A. I -- I -- as a general OB/GYN, I am not an academician, so I don't really read all of the literature. I trust the academicians to evaluate the literature and present that.

And so I trust those people who are

responsible for those to provide us with -- with informa- -- provide me with information and products that are trusted and available to be used. And that's -- that was my -- my belief with the Prolift® and Ethicon.

Q. (BY MR. FARRELL) Doctor, as part of your training in South Miami, were you shown any Prolift® implantation video?

A. I don't recall, but I think that -- I would -- I would believe that I was, again, just because that's the nature of how these courses were set up.

Q. As part of your training from Ethicon, were you ever told that -- to lay the mesh flat in the pelvic space during implantation?

A. I don't recall them using those specific words.

Q. Doctor, as part of your training from Ethicon, were you ever told that the mesh arms of the Prolift® could rope or curl due to tension of the arms when they were being pulled through the trocars?

MR. JOHNSON: Object to the form.

A. I don't recall it ever being specifically

mentioned.

Q. (BY MR. FARRELL) Doctor, during your training, did Ethicon ever inform you that there was an increased risk to patients from curling and roping of the Prolift® arms in the obturator space and the gluteal muscle tissue area?

MR. JOHNSON: Object to the form.

A. No.

Q. (BY MR. FARRELL) Doctor, during your training, did Ethicon ever inform you that as a result of any curling and/or roping of the Prolift® arms, that there could be an increased risk of scarring, contraction, erosion, and chronic pelvic pain for the recipient?

MR. JOHNSON: Object to the form.

A. No.

Q. (BY MR. FARRELL) Doctor, during the presentation from Ethicon, were you ever informed that they were aware that there were some patients who as a result of being implanted with the Prolift® would be left with lifelong pain and inability to have normal sexual relations as a result of the implantation?

MR. JOHNSON: Object to the form.

A. Well, that was part of the general risk of doing an anterior and posterior repair.

Q. (BY MR. FARRELL) A general risk was the possibility of having lifelong pain and inability to have normal sexual relations for the remainder of their life?

A. Yes. Even if you don't use mesh, that's a potential risk.

Q. Were you provided with any information from Ethicon regarding any data they had regarding the occurrence of any such risk?

MR. JOHNSON: Object to the form.

A. I don't recall.

Q. (BY MR. FARRELL) Doctor, during your training from Ethicon, were you ever informed that they were aware that there were some patients that would have contraction of the mesh and that the pain and the erosion and the complications resulting from any such contraction would not be able to be successfully treated and that those patients would be left with lifelong pain?

MR. JOHNSON: Object to the form.

A. Again, that goes along with the general risk for any type of anterior and posterior repair,

whether there's mesh or not. There's always that -- that chance of scarring, contracture, and pain and dyspareunia.

Q. (BY MR. FARRELL) But the possibility of contraction of the mesh is only a possibility when mesh is implanted, correct?

MR. JOHNSON: Object to the form.

A. Well, yes, if the mesh contracts. But the tissue -- the normal native tissue can also contract and scar.

Q. (BY MR. FARRELL) Were you told by Ethicon at the training you attended that scarring and contraction of the mesh was actually a positive aspect of the Prolift®?

MR. JOHNSON: Object to the form.

A. Scarring of the mesh was considered a benefit because that's how it reinforced the tissue and was what was responsible for the repair or the reduction of the cystocele and the rectocele.

Q. (BY MR. FARRELL) Did Ethicon inform you at your training that the contraction of the mesh could cause serious injury and that they were aware that, in fact, it would cause serious harm in some Prolift® patients?

MR. JOHNSON: Object to the form.

A. That was thought to be a very rare complication.

Q. (BY MR. FARRELL) And when did you come upon that understanding that that would be -- or that was thought to be a rare complication?

A. What?

Q. At what point in time?

A. That what was a rare complication?

Q. Your answer was that you believed -- or that was thought to be a rare complication.

A. What was thought to be a rare complication?

Q. The contraction of the mesh that could cause serious injury and would cause serious harm in some of Prolift® patients.

A. So when did they provide that information?

Q. When -- when did you become aware of that information? Yes.

A. Well, I think right from the very start.

Q. You -- you believe or you're sure?

A. No, I -- I'm not sure. You know, again, this was over 10 years ago.

But, again, these -- this was one of

the potential complications of the mesh surgery, although it was thought to be a very unusual, rare, infrequent complication.

Q. During your training, did Ethicon make you aware that if for some reason the Prolift® patients would have complications that required removal of the mesh, that it would be impossible for some patients to have the mesh removed in a safe and effective way and that their complications would therefore be on a permanent basis?

A. No, I never was aware of that fact.

MR. JOHNSON: And I'll object to the form.

Q. (BY MR. FARRELL) Is that information something that you would have wanted to be aware of in determining whether or not to use the Prolift® with one of your patients?

MR. JOHNSON: Ob- --

A. Yes.

MR. JOHNSON: Object to the form.

Q. (BY MR. FARRELL) Doctor, the -- the three cases you had on May 15th, 2007, where the physician from Corpus Christi was there to assist you, were they the first implantations of the Prolift® that

you undertook after the training in March of 2007?

A. Yes.

Q. Do you recall when after May 15th, 2007, that you first performed your own -- your first implantation of a Prolift® product by yourself without any assistance?

MR. JOHNSON: Object to the form.

A. I -- I don't know exactly, but I'm sure it was within the next couple weeks after that.

Q. (BY MR. FARRELL) Doctor, do you have a recollection of how many Prolift® implantations you performed prior to your implantation of Mrs. Dalberg on August 29th, 2007?

A. My estimate would be maybe -- maybe 10.

Q. And, Doctor, I believe you've already indicated, but there did come a time when you stopped implanting Prolift® into your patients; is that correct?

A. Yes.

Q. And what year was that?

A. I'm not sure of the specific year, but I imagine it was around 2010.

Q. And why did you stop using Prolift® in your patients at that point in time?

A. Well, actually, I probably stopped using Prolift® before that. I stopped using mesh completely in 2010 -- about 2010.

I stopped using Prolift® somewhere between probably 2008/2009. I'm not sure of the exact last time.

Q. And why did you stop using Prolift® at that point in time?

A. I started using a different product. As the different mesh products came out, I think they each had different advantages, and I ended up using or liking Boston Scientific's mesh at the end.

So all my cases at the end were -- I believe were Boston Scientific.

Q. Doctor, are you aware that Prolift® was pulled off the market in 2012?

MR. JOHNSON: Object to the form.

A. I knew that it was pulled off. I wasn't sure of the exact date.

Q. (BY MR. FARRELL) Are you aware why Prolift® was pulled off the market in 2012, Doctor?

MR. JOHNSON: Object to the form.

A. Because of the complications that have -- have arisen as for all mesh, I believe. I think

there's only one that's still available.

Q. (BY MR. FARRELL) And when you say "one," are you specifically referring to Ethicon product?

A. No. No, the only one that I know that's available, I believe, is still Boston Scientific.

Q. And, Doctor, are you fa- -- are you familiar with the FDA advisory committee hearing in September of 2011?

A. Yes.

Q. And do you understand that the FDA determined that the risk of pelvic organ prolapse surgeries outweighed the benefits and that it was only to be used as a matter of last resort?

MR. JOHNSON: Object --

A. Yes.

MR. JOHNSON: I'll object to the form.

Q. (BY MR. FARRELL) And, Doctor, are you aware that when the FDA determined that Ethicon would have to conduct the 522 studies, which would consist of randomized control trials to prove the safety and efficacy of the Prolift®, that they chose not to undertake those studies and instead take the product off the market?

MR. JOHNSON: Object --

A. No --

MR. JOHNSON: I'll object to the form.

A. No, I was not aware of that.

Q. (BY MR. FARRELL) Doctor, would it have been important to you in deciding whether or not to ever implant one of your patients with the Prolift® product that Ethicon had no randomized control trials proving the safety or efficacy of that device?

MR. JOHNSON: Object to the form.

A. That -- that -- I -- as -- again, as a general obstetrician/gynecologist, my -- my role is to rely on the experts, including Ethicon -- the people at Ethicon, to provide me with information on products that are safe and beneficial and are considered of good use for my patients.

As far as whether or not it's a random controlled trial study or a case cohort study or a case control study, what other -- what other -- what type of study they -- they need to do to provide that assurance that they are giving me a good product, a safe product, is up to them.

I'm not gonna be able to analyze a randomized controlled study and tell you whether or

not this is the answer.

I -- I rely on those academicians that are discussing those things, and I'm relying on the companies like Ethicon to obtain that information and provide that information so that we're getting a safe product that we can use for our patients.

Q. (BY MR. FARRELL) Doctor, were you aware that the Prolift® was sold from March 2005 until May 2008 without any FDA clearance?

A. No.

MR. JOHNSON: Object to the form.

Q. (BY MR. FARRELL) And during that time period when there was no FDA 510(k) clearance, that included the August 29th, 2007, surgery for Mrs. Dalberg; is that correct?

MR. JOHNSON: Object to the form.

A. Yes.

Q. (BY MR. FARRELL) If you were aware that the Prolift® had not received FDA clearance as of the date that you performed the surgery upon -- upon Mrs. Dalberg, would you still have recommended that the Prolift® be used for her?

A. I did not say -- I did not say that I was aware there was no FDA approval.

I said that -- yes to that as the time frame the surgery was. I was not aware that there was not an FDA approval.

Q. So if you had been aware that there was no FDA clearance for the Prolift® at the time that you implanted it in Mrs. Dalberg, would you have moved forward with recommending that that product be utilized for her?

MR. JOHNSON: Object to the form.

A. Yes, because there's a lot of things that are not FDA approved that we use.

And, again, I rely on the company -- the Ethicon company and their science people and their physicians and their -- their professors who are making this product available.

I, as a generalist, am relying on these acade- -- academicians that they are providing me with a safe, reliable, and beneficial product.

Q. (BY MR. FARRELL) Doctor, by the time that you stopped using Prolift® as part of your practice, approximately how many of the Prolift® products had you implanted?

A. I don't have any way to know that, but I can say it probably was at least 20 or 30.

Q. Doctor, as you continued to utilize the Prolift® as part of your practice, did you gain any additional knowledge of the risks or complications that came with the use of that product?

A. Yes.

Q. What specifically did you obtain new knowledge of?

A. Well, I noticed through my experience that my erosion rate was higher than what they had published.

Q. Anything else?

A. That's the main thing. I can't think of anything else specific to the Prolift®.

Q. And was that part -- was that part of the reason why you discontinued the use of the Prolift® product?

MR. JOHNSON: Object to the form.

A. No.

Q. (BY MR. FARRELL) And, Doctor, if you were aware -- aware of the erosion rate that you found to be higher in practice, if you had known about that higher rate than what the published rate was at the time that you counseled Mrs. Dalberg for her surgery, would you have still recommended the

Prolift® product to her?

MR. JOHNSON: Object to the form.

A. Well, first of all, the erosion -- the higher erosion rate wasn't just for the Prolift®. It was for all mesh, all the different ones that I've used. I noticed that my erosion rate seemed to be higher than what they were publishing.

And as far as Ms. Dalberg, she was not in that time frame when I noticed the higher erosion rate. She was one of the early procedures that I did, and my erosion rate at that point was still in line with what was published.

Q. (BY MR. FARRELL) But the question was if you -- with the knowledge of the higher erosion rate, if you were aware of that at the time that you counseled her regarding use of the Prolift®, would you have still recommended that product to her?

MR. JOHNSON: Object to the form.

A. I would have told her that I'm seeing a little bit higher erosion rates than what they're saying, and I would have counseled her on that and given her the choice to use it.

The -- but a lot of the erosions were very minor, and it just involved trimming the mesh

and suturing the epithelium closed. I do that in my office, and a lot of times that took care of the problem.

Q. (BY MR. FARRELL) Doctor, I believe you indicated that you used -- discontinued use of any mesh to address pelvic organ prolapse in 2010; is that correct?

A. That's an estimate. About 2010.

Q. Okay. Why did you make the decision to stop using mesh to address pelvic organ prolapse in approximately 2010?

A. The -- I believe the main reason was is because the -- the patients that were being referred to me were no longer being referred to me. They were being referred to the urologist.

The original referral source of patients that I had was from a urologist who did not do female urology, so he sent all the patients to me.

He retired and moved on. A new urologist came in, and so all those referrals were kept within the urology department because the new urologist did pelvic surgery.

Essentially, that pretty much ended my

referral source for these patients.

Q. Doctor, did you have any interactions with any sales representatives from Ethicon prior to your beginning to use the Prolift® product?

A. Yes.

Q. Do you recall the individual's name?

A. I don't remember her name, no.

Q. Okay. It was female, though?

A. Yes. I think her first name was Katie.

Q. Well, when in time do you recall having your first interaction with her?

A. I don't recall the first interaction, but I believe we were doing the Thermachoice endometrial ablations with Ethicon long before we were doing the Prolift®, I believe. I could be mistaken on that.

Q. Okay. Well, based upon your belief, then, that -- your first interaction would have been prior to the training in South Miami in March of 2007, correct?

A. I believe so.

Q. Were any other Ethicon products marketed to you in addition to the Prolift®?

A. The Thermachoice and the TVT®.

Q. After you became trained relative to the

Prolift®, did the sales representative begin to contact you regarding your use of that product in your patients?

A. Yes.

Q. And what specifically would the interaction consist of?

A. Oftentimes, the rep would come into the operating room with us and just kind of oversee the product and be there if we had any questions about the product.

Q. So the sales rep would be present at times in the operating room while you were implanting these Prolift® products?

A. I believe so, yes.

Q. And I believe you indi- -- you just indicated that the purpose of the representative being present was to provide advice, if necessary?

MR. JOHNSON: Object to the form.

A. Not advice, but just to help with the setup of the instruments and help with the -- I think oftentimes, the reps -- not just with Ethicon, but with other ones, would pull off the lot numbers and put them on the -- the chart.

Q. (BY MR. FARRELL) Did Katie play any role

in having you participate in the training in South Miami in March of 2007?

A. Well, if it wasn't Katie, it was one of the reps arranged for the -- me to get enrolled in the course.

Q. That was a male rep?

MR. JOHNSON: Object to the form.

A. That was what?

Q. (BY MR. FARRELL) That was a male representative?

A. No. I think it was Katie or someone. I don't remember.

Q. Okay.

A. I don't remember who exactly introduced me to the course.

Q. Did Katie or any other representative attend a training with you in South Miami?

A. I do not believe so.

Q. Do you still have any dealings today with any Ethicon sales representatives?

A. No.

Q. Do you still perform the ablation procedures?

A. Not that one.

Q. You perform a different one at this point in time?
A. Correct.
Q. And does that utilize a product from a different company?
A. Yes.
Q. And what was the reason you changed from Ethicon to the new company for the ablation product?
A. I liked the procedure better.
Q. And what company is that?
A. I'm not really sure. It's the hydro ablation. It may be AMS. I'm not sure.
Q. Did Katie or any other Ethicon representative ever provide you with Ethicon materials relating to the Prolift® product?
A. Yes.
Q. What type of materials?
A. Literature, brochures, training videos.
Q. What type of brochures were they?
A. Patient brochures. Patient information brochures.
Q. Do you have any recollection of Katie or another representative and yourself going through the patient brochures in order -- with you in order

to explain what information was contained in those brochures?

A. No.

Q. No, you don't recall, or, no, it did not happen?

A. I don't believe it happened. I mean, I could go through the brochures myself and read them and then provide them to the patients.

Q. Did Katie or any other Ethicon sales representative ever go through any physicians' marketing materials with you?

A. I imagine they did. That was part of why I got the brochures.

Q. Did Katie or any other Ethicon sales representative ever go through the Prolift®, IFU or Instruction For Use booklet with you?

A. No.

Q. Do you recall ever speaking with Katie or any other Ethicon sales representative regarding any warnings that Ethicon had issued relative to the Prolift® product?

A. I don't recall.

Q. And did Katie or any other Ethicon representative ever compare any of the Prolift®

products to any other manufacturers' pelvic floor repair products with you?

A. I don't recall.

Q. Do you recall ever having any questions or concerns with any of the mesh products from Ethicon, including the Prolift®, that were addressed by Katie or any other Ethicon sales representatives?

A. I don't recall.

Q. Do you currently use any Ethicon product as part of your practice?

A. Suture.

Q. What about the mesh slings that you referenced earlier, what company do you use, mid- --

A. I'm not su- --

Q. -- mid-urethral slings, I believe you said?

A. I'm not sure which sling the hospital has.

The number of slings I do per year is less than six, and the one who does most of the slings are the urologists, and so when I do a sling, I have the urologist assist me because I do so few of them.

Q. Earlier during your testimony you in- -- you indicated that you decided to use the Prolift®

because it was most available to you and it was the one that you had the most training in.

Do you recall that testimony?

A. Yes.

Q. How was the Prolift® product most available to you?

A. Well, at that time, I think that Bard and Prolift® were the only two that were out -- out there, and so I'm not sure that the other companies really had established their -- their product line. I know that it was fairly soon after that the others -- others had theirs.

So it was just the one that was -- I had the most information about. They were the one that sent me to the course. They were the one that provided me with the proctor.

So I -- I had a lot of good information and good training on -- on their system. So I felt most comfortable using something that I had seen and actually had had a chance to actually apply it in a cadaver or lab situation.

And then had a proctoring physician, a experienced surgeon, be able to assist me on my first three cases to kind of just sort of complete

the training that I needed in order to have the product.

So Ethicon provided all that training, and it was with their Prolift®.

Q. Doctor, when you stopped using the Prolift® product, did Katie or any other Ethicon representative express any concern to you about your stopping the use of that product?

A. I don't believe so. Actually, I don't remember any.

Q. Doctor, do you agree that in order to determine whether a medical device is safe and effective, the device must be adequately studied?

MR. JOHNSON: Object to the form.

A. Yes.

Q. (BY MR. FARRELL) Doctor, do you agree that the best way to determine whether a medical device is safe and effective is for a manufacturer to conduct randomized controlled trials of the device?

MR. JOHNSON: Object to the form.

A. I'm not sure if that's the best way. I mean, those are certainly good studies, but it doesn't necessarily mean that that's the best.

And, again, I am not an academic physician. I'm a -- I'm a worker bee out there in the field taking care of these patients, and so I rely on those academic people that are doing these studies to determine which type of study is gonna be the most appropriate and the best.

Q. (BY MR. FARRELL) Doctor, did you believe at the time that you recommended the Prolift® product to Mrs. Dalberg that Ethicon had ade- -- adequately studied the Prolift® product in order to determine that it was both safe and effective?

A. Yes.

Q. Doctor, do you rely upon the manufacturer of a product, at least in part, to provide you with adequate warnings regarding the serious health hazards associated with its product so that you can adequately inform patients of any serious hazards?

MR. JOHNSON: Object to the form.

A. That's essential. I mean, that's the only way I can practice medicine is to have that information to relay to the patients.

Q. (BY MR. FARRELL) I'm sorry, Doctor. Did you say "that's essential"?

A. It's essential. Yes.

Q. You're blipping out a little bit.

You said "essential," correct?

MS. HARRIS: Correct.

A. Yes.

Q. (BY MR. FARRELL) Okay. Doctor, at the time of the Prolift® implant with Mrs. Dalberg, did you rely on Ethicon's Instructions For Use, at least in part, to help inform her about the hazards associated with the device?

MR. JOHNSON: Object to the form.

A. Can you repeat the question?

Q. (BY MR. FARRELL) Yes.

At the time of the surgery with Mrs. Dalberg, did you rely, at least in part, on the Instructions For Use from Ethicon in order to be able to inform Mrs. Dalberg about the possible serious hazards that could be associated with the device?

MR. JOHNSON: Object to the form.

A. I wouldn't say I used the instructions. The instructions, to me, what you're asking -- I mean, the instructions basically tell you how to use -- how to insert the product.

Q. (BY MR. FARRELL) Right.

And then also the Instructions For Use, which we'll get to in a little bit, also sets out warnings and precaution, adverse reactions, that type of information?

A. I did not use the instruction sheet for that. I used my -- my consent -- informed consent to discuss the -- the adverse potential risks.

Q. Doctor, what sources of information did you use prior to counseling Mrs. Dalberg about the risks and benefits of the Prolift® implantation surgery?

A. Can you repeat the question?

Q. Yeah.

(Phone interruption.)

Q. (BY MR. FARRELL) What -- what sources of -- sources of information did you use prior to counseling Mrs. Dalberg about the risks and benefits of the Prolift® implantation surgery?

A. All my training from residency and all my experience in practice regarding anterior and posterior repairs and all of my education I received from the training from Ethicon, all of that goes into providing an informed consent.

Q. Doctor, you were -- you were familiar with

the Instructions For Use prior to moving forward with the surgery upon Mrs. Dalberg, correct?

A. Now, the "Instructions For Use," what do you mean for that? Are you talking about that pamphlet?

Q. Yes.

MR. JOHNSON: Well, object to -- I'm gonna object to the form.

A. The -- the little booklet that you just kind of showed was -- was -- I believe that's the Instructions For Use which comes with the -- the -- each -- each kit, and I already knew that -- the information that I needed in order to perform an informed consent. I did not use that pamphlet for doing that.

Q. (BY MR. FARRELL) Right.

But my question was: Were you -- were you familiar with the Instructions For Use? You indicated earlier that you believed you reviewed it as part of your training in South Miami.

MR. JOHNSON: Object to the form.

A. I don't believe that particular manual was -- that you're showing was part of the training in South Florida.

When I -- when you said Instructions For Use, I'm talking about instructions for using the -- for the product, not necessarily that pamphlet.

Q. (BY MR. FARRELL) What about the patient brochure that you referenced earlier? Was that a source of information that you utilized when you counseled Mrs. Dalberg regarding the surgery?

A. No. When I -- when I counsel patients for this surgery, again, I'm using my training in residency, my urogynecology training in residency, my experience, reading the textbooks that I use, and the training that I'm getting in these courses that I go to. All of that information together goes to obtain the informed consent.

Q. Did you offer Mrs. Dalberg any other surgical options besides the Prolift® mesh?

A. Yes.

Q. What -- what were the other surgical options that you offered?

A. The traditional anterior repair. I offer that to -- to everybody. I give them the option of not using the mesh or using the mesh.

Q. Did you offer any nonsurgical options?

A. I always offer physical therapy and I always discuss pessary as therapeutic options for pelvic prolapse.

Q. Doctor, in order for you to be able to counsel your patients on available options to treat pelvic organ prolapse, is it important for you as the implanting physician to be aware of all the potential risks associated with the use of the product that you're using to implant?

A. Yes.

MR. JOHNSON: Object to the form.

Q. (BY MR. FARRELL) And, Doctor, your -- your knowledge of all potential risks relating to a specific product is part of the risks/ben- -- risk/benefit analysis that you provide to your patients, correct?

A. Correct.

Q. Doctor, do you expect that a manufacturer such as Ethicon would provide you with the information that you would need to know in order to understand all risks --

MR. JOHNSON: Object --

Q. (BY MR. FARRELL) -- risks that are inherent in using their product?

MR. JOHNSON: Object to the form.

A. It's crucial that they give me that information.

Q. (BY MR. FARRELL) Doctor, would you expect for a manufacturer such as Ethicon to be completely truthful with you about the risks associated with their product that you're using?

A. It's essential. I mean, I rely on these companies to provide me with the information that I need to appropriately counsel my patients. I mean, there's just no other way I could get that information. I have to get it from the companies.

MR. FARRELL: Let's go off the record real quick so we can get the two exhibits I want to use, please.

MR. JOHNSON: Sure. Could we take a short break?

THE VIDEOGRAPHER: Going off the record. Time is 3:54.

(A recess was taken from 3:54 p.m. to 4:04 p.m.)

THE VIDEOGRAPHER: Back on the record. Time is 4:04.

(Line intentionally left blank.)

(Deposition Exhibit 13 marked for identification.)

MR. FARRELL: Could you please hand the doctor Exhibit 13, please.

MS. HARRIS: He's got it.

MR. FARRELL: Okay.

Q. (BY MR. FARRELL) Doctor, Exhibit 13 is the Prolift® IFU or Instruction For Use that was in effect at the time of the surgery on Mrs. Dalberg.

A. (Examined exhibit.)

Q. Doctor, is this a document that you were familiar with or you saw back when you were still using the Prolift®?

A. I'm sure I did. I don't recall at this point, but I'm sure this is the one that was given to us.

Q. Okay. And this IFU booklet would be included with every -- every box that had the Prolift®; is that correct?

A. Yes.

Q. I just wanted to ask you a few -- few questions about the document.

If you'd go to page 2, please.

A. (Complied.)

Q. There's a section headed "GYNECARE GYNEMESH PS."

Were you aware that the trade name internally of the Prolift® mesh was Gynemesh™ PS?

A. No.

Q. Okay. If we could go down to the third line under the "GYNECARE GYNEMESH PS," about the middle of the line it sets out, "The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth."

Do you see that, what I just read, Doctor?

A. Yes.

Q. Doctor, did you assume that for Ethicon to make that statement that they would have had clinical data to support that statement regarding the Prolift® mesh?

A. Yes.

Q. Doctor, regarding sufficient porosity for necessary tissue ingrowth, were you ever told that Ethicon knew that the pores, due to their size, could allow scar tissue to go across them and cause something called fibrotic bridging and scar plating

which would make the mesh rigid and hard?

MR. JOHNSON: Object to the form.

A. No.

Q. (BY MR. FARRELL) Doctor, if you had been informed of that, would that have impacted your decision as the implanting surgeon regarding whether or not to use the Prolift® in your patients?

MR. JOHNSON: Object to the form.

A. It depends on what the significance of that is. That happens, but how significant is that?

Q. (BY MR. FARRELL) Okay. Doctor, the last line of that paragraph it sets out, "The bi-directional elastic property allows adaptation to various stresses encountered in the body."

Do you see that?

A. Yes.

Q. Doctor, did you presume that Ethicon had a clinical data to support that claim?

MR. JOHNSON: Object to the form.

A. I would assume that anything they say in their product would be backed up with some form of evidence for them to make that statement, including this one.

Q. (BY MR. FARRELL) And, Doctor, the fact

that Ethicon claimed that the Prolift® mesh could adapt to the stresses encountered in a woman's pelvis, did that seem to be a good thing and something that made the Prolift® a product that you would want to use in your patients?

MR. JOHNSON: Object to the form.

A. Well, I'm not really sure exactly what that means and what the significance of it is.

And I didn't necessarily rely on this -- this pamphlet to help me decide whether or not this was something I wanted to use for my patients.

Q. (BY MR. FARRELL) Doctor, if you could turn your attention, please, to Page Number 5 under the heading "PERFORMANCE" towards the bottom. It sets out that, "Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by a deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adja- -- adjacent tissue."

Do you see that, Doctor?

A. Yes.

Q. Did you presume that Ethicon had clinical data to support those statements and claims about the mesh and how it would actually behave in use?

A. Well, clinical data or some type of laboratory data to -- for them to make the assertion.

Again, anything they say in this pamphlet, I would expect that they would have some reason for saying this.

Q. And with regards to the "minimum to slight inflammatory reaction," do you believe that information to be true?

A. I do believe that there's an inflammatory reaction caused by any foreign body placed in the -- in the body.

Q. Okay. Did Ethicon ever inform you that they were aware that the mesh would not cause a minimum to slight inflammatory reaction which is transient in all patients, but that, in fact, they knew that in all patients, the inflammatory reaction would be ongoing, and for some patients the inflammatory reaction would be severe?

MR. JOHNSON: Object to the form.

A. Some patients or all patients?

Q. (BY MR. FARRELL) Some.
A. No, Ethicon never informed me of that.
Q. Doctor, would it be true that the -- the body's foreign body response would be ongoing as long as the foreign body mesh is still present?
MR. JOHNSON: Object to the form.
A. Well, not necessarily. I mean, mesh is used in many parts of the body for surgery and there's not necessarily a continuing inflammatory reaction.
I mean, mesh is used for abdominal hernia repairs.
Mesh is used for sacrospinous fixation.
We use mesh for laparoscopic Burch procedures.
So it doesn't necessarily mean that there's going to be an ongoing inflammatory response.
Q. (BY MR. FARRELL) But there could be, correct?
MR. JOHNSON: Object to the form.
A. There could be.
Q. (BY MR. FARRELL) And, Doctor, you saw the

language regarding the thin fibrous layer of tissue, correct?

A. Correct.

Q. And if that's a common awareness that for some patients a thick hard layer of tissue would grow across the mesh, which would cause pain and other complications, would you have wanted to be told that?

MR. JOHNSON: Object to the form.

A. Well, pain and complications is already a known complication of -- of the mesh, and that's already in the informed consent, and that's part of the -- just the graft rejection is a rejection by an inflammatory response or an immune rejection.

So I think -- you know, again, how many patients? Is it 40 percent or 60 percent?

My understanding was that it was an unusual -- and in my experience, it was a very unusual occurrence.

Q. (BY MR. FARRELL) But the language set out in the IFU refers to a thin fibrous layer of tissue, whereas they had knowledge that there would be, in some patients, a thick hard layer of tissue that would grow across the mesh.

Is that something that you would have wanted to have known?

MR. JOHNSON: Object to the form.

A. Well, I think I already did know it. I mean, I already knew that that happened in some patients.

And, again, that's part of the informed consent for rejection of the -- the mesh and -- and scarring, which could potentially cause pain and would potentially have to be removed.

Q. (BY MR. FARRELL) Doctor, there's the statement that, "The mesh remains soft and pliable."

(Phone interruption.)

Q. (BY MR. FARRELL) Do you see that?

A. (Examined exhibit.)

Q. Second-to-last sentence?

A. Which page?

Q. Page 5 still.

A. Okay. Yeah, I see it.

Q. Did you assume that when Ethicon made that statement regarding the mesh remaining soft and pliable in actual use, did you believe that they had clinical data to support that and that that was a truthful statement?

A. Or laboratory. Some -- some reason why they can make that statement. I would assume they have -- whether it's laboratory or clinical.

Q. Was it important to you that, according to Ethicon, the Prolift® mesh would remain soft and pliable in your patients' vaginal tissue?

MR. JOHNSON: Object to the form.

A. I mean, I'm not really sure that I ever really thought about whether or not it remained soft and pliable.

Q. (BY MR. FARRELL) Doctor, if you were informed that, in fact, the mesh does not remain soft and pliable, but in many patients can become rigid and hard and as a result cause problems, would that have been important to you to know?

MR. JOHNSON: Object to the form.

A. Well, again, I want to know what the -- what the frequency of that is, how often does that happen, and why does it happen, and to be able to let the patient know that this is a potential risk, and as a result of that, may have to be removed.

But, again, the informed consent already covers scarring and potential reaction and potential removal. So I felt like -- like the -- we

were telling the patients that this is a possibility, but a low possibility.

Now, if it turns out that it's a much higher possibility and -- than -- than what -- what we were -- what I was led to believe, then that certainly is important information to know.

Q. (BY MR. FARRELL) Well, Doctor, if we can turn your attention to page 6 under "Warnings and Precautions."

A. (Examined exhibit.)

Q. The fourth bullet point sets out, "Avoid placing excessive tension on the mesh implant during handling."

Do you see that?

A. Yes.

Q. Were you ever provided with any information from Ethicon regarding a quantification for how much tension would be considered excessive when you were implanting the Prolift® product?

A. Well, we -- we kept it tension-free, so there was no tension in the -- the arms of the mesh.

So basically, no tension was the correct tension.

Q. From the information that you received

from Ethicon, was it your understanding that once the mesh was implanted inside the body, there would be some contraction and tension and that would actually be a good thing that would help the Prolift® operate properly?

A. Yes.

Q. Did anyone from Ethicon ever indicate to you that they believed placing any tension on the mesh once it was inside the body would actually be reason to cause harm to the patient?

MR. JOHNSON: Object to the form.

A. No.

Q. (BY MR. FARRELL) Doctor, in reviewing the IFU document, is there anything contained in the IFU that describes or instructs the physician regarding any surgical technique to be utilized if excision or removal of the mesh is necessary?

A. (Examined exhibit.) In reviewing the document, I do not see any.

Q. Doctor, regarding any decision to recommend surgery for excision or removal of the Prolift® product, were you left to your own judgment, based upon the fact that Ethicon provided no instructions on the best way to remove the

product, if necessary?

A. Yes.

Q. And if Ethicon had information in its possession regarding the advisability of undertaking an excision or removal surgery of the Prolift®, would you have liked to have had that information available to you?

MR. JOHNSON: Object to the form.

A. Yes.

Q. (BY MR. FARRELL) Was any information regarding the effectiveness and risks of repair surgery ever provided to you by Ethicon regarding the Prolift®?

A. Can you repeat the question?

Q. Did Ethicon ever provide you with any information regarding the effectiveness and risks of repair surgery, excision surgery, relating to the Prolift® product?

A. No. No.

(Deposition Exhibit 14 marked for identification.)

MR. FARRELL: Would you please hand the doctor Exhibit 14.

MS. HARRIS: You got it?

THE WITNESS: Uh-huh.

MS. HARRIS: He's got it.

Q. (BY MR. FARRELL) Doctor, you made reference earlier to being provided patient brochures from the Ethicon representative that interacted with you.

Do you recall that testimony?

A. Yes.

Q. Does Exhibit 14 look familiar to you regarding a brochure that would have been provided to you to pass on to your patients?

A. No, it does not. But I can't say this was not one that they gave me. It's just I -- I don't remember.

Q. I'll represent to you that this is one of the brochures that was in circulation at the time of your surgery upon Mrs. Dalberg in 2007.

A. It's very likely, then, this is the one that I would have used.

Q. And, Doctor, I believe you indicated that you did provide brochures to your patients; is that correct?

A. Correct.

Q. And, Doctor, did you presume that these

brochures that were provided to you by Ethicon would include truthful and accurate information concerning the Prolift® procedure?

A. Yes.

Q. And did you presume that Ethicon would be providing fair and balanced information about the Prolift®?

A. Yes.

Q. Meaning any positive asp- -- and negative aspects for your patients?

A. Well, I would like to say they would pro- --

MR. JOHNSON: Object to the form.

A. I would like to say they would provide honest information.

Q. (BY MR. FARRELL) Doctor, if I could direct your attention to page 10 of the I- -- of the patient brochure.

A. (Complied.)

Q. There is the heading where it says "What is GYNECARE PROLIFT?"

Do you see that, Doctor?

A. Yes.

Q. And underneath it, it says -- or sets out,

"A revolutionary surgical procedure using GYNECARE PROLIFT employs a specially designed supportive soft mesh placed in the pelvis to restore pelvic support."

Do you see that, Doctor?

A. Yes.

Q. When you see that information, did you presume that Ethicon was providing truthful information when they stated that the Prolift® used a specially designed supportive soft mesh?

MR. JOHNSON: Object to the form.

A. Yes.

Q. (BY MR. FARRELL) If we go to page 13, Doctor.

A. (Complied.) Okay.

Q. And under "What are the risks," it sets out, "All surgical procedures present some -- present some risks. Although rare, complications associated with the procedure . . ." and it sets out the complications.

Do you see that, Doctor?

A. Yes.

Q. And when Ethicon made that representation in the brochure that complications with the product

were rare, did you believe that they were representing truthful information based on all the data that they had available to them?

MR. JOHNSON: Object to --

A. Yes.

MR. JOHNSON: -- object to the form.

Q. (BY MR. FARRELL) And when Ethicon made that statement regarding complications being rare, did you presume that they had clinical data that proved that to be a true statement?

A. Yes.

Q. Doctor, earlier you gave some testimony relating to the Operative Report of August 29th, 2007, of Exhibit 9.

Do you recall that testimony?

(Phone interruption.)

A. What exact- -- I don't recall the testimony that I gave.

Q. (BY MR. FARRELL) Well, just -- you -- I believe you indicated, correct me if I'm wrong, that you had the opportunity to read over the Operative Report as part of your preparation for today's deposition?

A. Yes.

Q. Okay. And based upon your review of the report, were there any complications during your surgical procedure with Mrs. Dalberg?

A. I did not notice any complications in the report. So, no, I didn't see any.

Q. And after having reviewed your Operative Report and with the information that's contained within the Instructions For Use, do you believe that you performed the Prolift® implantation surgery correctly on August 29th, 2007?

A. Yes.

MR. FARRELL: All right, Doctor. That's all the questions I have for now.

I'll reserve the remainder of my time. Thank you.

MR. JOHNSON: Let's go off the record.

THE VIDEOGRAPHER: Going off the record. Time is 4:26.

(A recess was taken from 4:26 p.m. to 4:31 p.m.)

THE VIDEOGRAPHER: Back on the record. Time is 4:31.

(Deposition Exhibit 15 marked for identification.)

FURTHER EXAMINATION

BY MR. JOHNSON:

Q. Doctor, could you take a look at what we've marked as Exhibit Number 15, which is a June 5th, 2012, letter from Ethicon to healthcare providers?

A. Okay.

Q. Do you know whether you've seen that letter before?

A. I may have.

Q. There was reference by counsel that somehow the Prolift® was, quote, "pulled off the market," end quote, and I'd like for you to take a look at --

MR. FARRELL: Form.

Q. (BY MR. JOHNSON) -- the third paragraph of Exhibit Number 15 and read that to yourself.

A. Okay.

MR. FARRELL: Objection to form.

Q. (BY MR. JOHNSON) Looking at the third paragraph, does -- what does that indicate to you as to whether or not Ethicon made a decision to stop selling the product, decommercialize the product?

A. What's the question?

Q. Does -- and also, if you could take a look at the fifth paragraph.

A. Okay.

Q. Could you just read the first two sentences of the fifth paragraph of the letter.

A. "We want to emphasize that we continue to have confidence" --

MR. FARRELL: Objection.

A. -- "in the safety and efficacy of these products. This is not a product recall."

Q. (BY MR. JOHNSON) And then in look- -- having looked at the third paragraph as well, does it appear that the company made a decision to decommercialize their product or just stop selling it?

A. Yeah, it seems like it was a commercial decision.

MR. FARRELL: Objection to form.

Q. (BY MR. JOHNSON) All right. Is there anything in that letter that you've had a chance to review that indicates to you that this was somehow pulled off the market?

A. No.

(Deposition Exhibits 6 - 12

referenced.)

Q. (BY MR. JOHNSON) Doctor, if you could take a look at records, pages -- or numbers -- Exhibits 6 through 12. I think you've already had a chance to look at them. You probably don't have to look at them again. I just want to authenticate these records.

A. (Examined exhibit.)

Q. Do the Exhibits 6 through 12, which are the medical records, appear to be true and correct copies of medical records pertaining to your care and treatment of Ms. Dalberg in late August, early September 2007?

A. Yes.

Q. Do you have any reason to believe these records are unreliable?

A. No.

Q. Are these records that would have been maintained -- kept and maintained by the hospital in the ordinary course --

A. Yes.

Q. -- of their business?

A. Yes.

Q. And are there records that you've made

entries on, records in which the entries were made at or about the time of the occurrence?

A. Yes.

Q. All right. There was a question by counsel about the need to have the Prolift® mesh lie flat in the abdomen when it was placed.

A. In the abdomen or vagina?

Q. In -- well, in the vagina -- strike that.

Let me ask you the question.

When you placed the -- the Prolift® during the pelvic organ prolapse surgery, did you lie it flat?

A. Yes.

Q. And why did you do that?

A. Well, I just -- again, I'm trying to recreate that tent to hold the rectum in place or recreate the hammock to hold the bladder in place, so you want it flat.

Q. You mentioned that you had stopped using the Prolift® and then started using a Boston Scientific product.

A. Well, I went from -- I've used AMS. I use Boston Scientific. I kind of experimented with all of them.

Q. And my question is: Did you stop using the Prolift® because of concerns you had regarding safety or effective- -- effectiveness of that product?

A. No.

Q. Then I don't know if counsel mentioned this or -- I just want to make sure that the record's clear.

The company produced information regarding training -- to -- to plaintiffs' counsel regarding trainings that you had with respect to their products.

A. Okay.

Q. And he referenced the training you had in March of 2007 at -- at South Miami.

A. Um-hum.

Q. And he referenced the training at Metroplex Hospital in May of 2007.

A. Um-hum.

Q. According to the information we provided to plaintiffs' counsel, you also had training in TVT® and TVT-O in May of 2002 in Overland Park.

A. Yes.

Q. Do you recall that?

A. Yes.

Q. At Overland Park Regional Hospital?

A. Yes.

Q. When you had that training, did you -- could you tell the jury what kind of training you received when you had the TVT-O and TVT® training, and tell them what that means?

A. Well, back -- again, generally speaking, it included a didactic session discussing the -- the benefits of the mid-urethral sling and discussed the insertion of it and probably had some instructional videos.

And then following that, there was probably some kind of cadaver lab where we actually went in and got hands-on experience in placing the TVT®.

Q. Does TVT® stand for tension-free vaginal tape?

A. Transvaginal tape.

Q. All right. And then after 2000 -- after that training that you had in the TVT® and TVT-O in 2002, did you start putting in Ethicon mid-urethral slings?

A. I didn't really start doing the TVT® for a

while after that because it really wasn't widely -- it wasn't used widely where I was at. And the initial practice that I was at -- I was at when I went to that course, the urologists were doing all of the sling procedures.

So although I had wanted to use it, it -- I wasn't in a situation where it was part of my practice at that point.

Q. At some point in time, did you use the TVT® and TVT-O manufactured by Ethicon?

A. Yes.

Q. Approximately how many of those slings did you put in?

A. I did a lot of slings. Almost every time we did a vaginal vault reconstruction, it included a TVT® or TOT.

Q. Doctor, when we take a look at the consent form that you prepared, which is the Exhibit Number 7, and specifically the last two pages of Exhibit Number 7, the Pelvic Reconstruction Consent, those two pages are pages that you -- you and your office prepared; is that right?

A. Correct.

Q. My question --

MR. FARRELL: Objection.

Q. (BY MR. JOHNSON) My question is: How did you go about preparing your own consent form that's represented in this Pelvic Reconstruction Consent?

MR. FARRELL: Objection.

A. This consent form, I believe, was given to me from one of the courses that I attended, and so I -- I essentially took the consent form that was being used by one of the universities and sort of modified it to -- tailored it to our needs, our specific needs.

Q. (BY MR. JOHNSON) Did you rely on the IFU regarding Prolift® at all in preparing this consent form?

A. No.

Q. You mentioned that -- or strike that.

I think you mentioned that you noted that your practice, you were getting a higher rate of exposure with mesh products than the rate that you'd been told?

A. Higher rate of erosions.

Q. Okay. Erosions.

And my question is: In your clinical experience, did you think that you were getting a

higher rate of erosions with the Prolift® as opposed to the other meshes?

A. No.

Q. What was the -- what was the rate that you -- when you first started using the products, meshes of all kinds from different companies, what was the exposure rate that you -- or erosion rate you were expecting?

A. You know, I can't remember. I --

MR. FARRELL: Objection.

A. -- I think it was around 5 percent, and I felt like I was seeing a lot more than that.

Q. (BY MR. JOHNSON) And were you able to put a percentage on how much more you were seeing?

A. I think I was seeing around 20 percent. So -- and a lot of them were very minor, and it just -- it just took a little bit of trimming and then re- -- and then closing up the -- the vaginal tissue over the trim, and that seemed to take care of it.

But it did seem like it was, in my mind, higher than what was being broadcasted to me by the -- by the products.

Q. These erosions that you're -- that you saw

through the vaginal tissue, were they related to -- mainly to TV- -- to the mid-urethral slings or to the mesh used for pelvic organ prolapse? Was one more prominent?

A. Very rarely --

MR. FARRELL: Objection.

A. -- did I see an erosion from the mid-urethral slings. That was a very uncommon event.

It was more of the posterior. It seemed to be the posterior repair which had more of the erosions.

Q. (BY MR. JOHNSON) All right. Doctor, if you could take a look at Exhibit 14 again, which is the patient brochure.

A. (Examined exhibit.)

Q. As you sit here today, are you able to say under oath that that specific brochure was available in your office at the time that Ms. Dalberg would have been getting her informed consent?

A. I cannot say that.

Q. All right. Doctor, just in wrapping up, did you believe -- or strike that.

What was your belief as to the

clinical experience that your patients generally had with Prolift®?

A. Generally --

MR. FARRELL: Objection.

A. -- I thought it was a favorable experience. I thought most of the patients were -- were happy with the procedure and most of the patients got benefit from it.

Q. (BY MR. JOHNSON) Did you draw any conclusions as to whether or not patients had improved quality of life after having the Prolift® surgery for their prolapse?

A. I felt -- I felt like --

MR. FARRELL: Objection.

A. -- most of them did.

Q. (BY MR. JOHNSON) And then when you -- at the time that you implanted the Prolift® mesh into Ms. Dalberg, was it your belief that the benefits outweighed the risks?

A. Yes.

But that wasn't my decision. It was the patient's decision, and the patient had to make that decision for themself.

And, you know, we -- again, we

discussed the risks and the benefits. She had already had one repair, traditional repair, that failed.

So, I mean, these were her options -- any patient's options, and they ultimately have to make that decision. It really doesn't matter what I think. It's really what they decide for their own personal healthcare.

Q. In your hands, Doctor, do you have an opinion whether the Prolift® was safe and effective for the treatment of pelvic organ prolapse in your patients?

MR. FARRELL: Objection.

A. I don't really have an opinion on that because, again, that's beyond -- that -- that type of question has to be studied by people who do these studies, and they have to come up with the answers on those.

I felt the product was a reasonable way to take care of the problem, and I used the product and I thought it was a good concept, and it doesn't seem to have worked out because it's not available anymore, and my only -- my only conclusion is that with clinical experience, they have shown

that it's not safe to use anymore, and that's why it's not used anymore.

Q. (BY MR. JOHNSON) Do you have any knowledge to support the state- -- the statement that the Prolift® is not safe to use, any clinical data?

A. The -- no. The only -- again, I'm not gonna analyze all ten papers that are out there.

But the -- the academicians who are looking at this and making their recommendations have said -- have come out and said, based on that FDA -- and as -- by that FDA recommendation, that it's not to be the first choice. It's to be used in certain situations, so . . .

Q. All right.

MR. JOHNSON: Thank you. That's all the questions that I have, Doctor.

MR. FARRELL: I have no further questions. Thank you.

THE VIDEOGRAPHER: This concludes the deposition of Dr. Mark Lobaugh. Going off the record. Time is 4:45.

(Off the video record.)

MR. JOHNSON: Thanks, Doctor.

THE COURT REPORTER: Would you like the Doctor to read and sign?

MS. HARRIS: Yes. And you can send the original to me, and I'll get it to him.

(Deposition concluded at 4:45 p.m., September 26, 2018.)

CHANGES AND SIGNATURE

WITNESS NAME: MARK L. LOBAUGH, M.D.

DATE: DATE, 2018

PAGE/LINE	CHANGE	REASON

I, MARK L. LOBAUGH, M.D., have read the foregoing deposition and hereby affix my signature that same is true and correct, except as noted above.

_____

MARK L. LOBAUGH, M.D.

THE STATE OF _____)

COUNTY OF _____)

Before me, _____, on this day personally appeared MARK L. LOBAUGH, M.D., known to me (or proved to me under oath or through _____) (description of identity card or other document) to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that they executed the same for the purposes and consideration therein expressed.

Given under my hand and seal of office this _____ day of _____, 2018.

_____

NOTARY PUBLIC IN AND FOR

THE STATE OF _____

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,	)	Master File No. 2:12-MD-02327 MDL No. 2327 HON. JOSEPH R. GOODWIN, U.S. DISTRICT JUDGE
REBECCA DALBERG, ET AL, Plaintiffs, v. ETHICON, INC., ET AL., Defendants.	)	Case No.: 2:13-cv-09725

REPORTER'S CERTIFICATE

DEPOSITION OF MARK L. LOBAUGH, M.D.
TAKEN DATE, 2018

I, Karen L. D. Schoeve, Certified Shorthand Reporter, Registered Diplomate Reporter, Certified Realtime Reporter, and Realtime Systems

Administrator, residing in the State of Texas, do hereby certify that the foregoing proceedings were reported by me and that the foregoing transcript constitutes a full, true, and correct transcription of my stenographic notes, to the best of my ability and hereby certify to the following:

That the witness, MARK L. LOBAUGH, M.D., was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to JEFFREY R. JOHNSON, custodial attorney;

That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

I further certify that pursuant to FRCP No. 30(f)(i) that the signature of the deponent was requested by the deponent or a party before the completion of the deposition and the signature is to be returned within 30 days from date of receipt of the transcript.

If returned, the attached Changes and Signature Page contains any changes and the reasons therefore;

I further certify that I am neither counsel for, related to, nor employed by any of the parties in the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Subscribed and sworn to on this the 10th day of October, 2018.

_____

Karen L. D. Schoeve, CSR, RDR, CRR
Realtime Systems Administrator
NCRA Certification Exp. 09/30/18
Golkow Litigation Services
Firm Registration No. 690
One Liberty Place
1650 Market Street, Suite 5150
Philadelphia, Pennsylvania 19103
T: 877.370.3377
F: 917.591.5672
www.golkow.com